

FILED  
U.S. DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
05 JUN 24 PM 3:57  
LAURENCE  
GLENN

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

1 : 05-cv-0951 -JDT-TAB

MOUSSA YEROUSHALMI, On Behalf of  
Himself and All Others Similarly Situated,

Plaintiff,

§  
§  
§  
§  
§

Civil Action No. \_\_\_\_\_

vs.

GUIDANT CORPORATION, RONALD W.  
DOLLENS, KEITH E. BRAUER GUIDO J.  
NEELS, BEVERLY H. LORELL, RONALD  
N. SPAULDING, AND WILLIAM F.  
MCCONNELL JR.,

**JURY TRIAL DEMANDED**

Defendants.

**CLASS ACTION COMPLAINT FOR VIOLATIONS  
OF FEDERAL SECURITIES LAWS**

This writing/publication is a creative work fully protected by all applicable copyright laws, as well as by misappropriation, trade-secret, unfair-competition and other applicable laws. The authors of this work have added value to the underlying factual materials herein through one or more of the following: unique and original selection, coordination, expression, arrangement, and classification of the information. No copyright is claimed in the text of statutes, regulations, and any excerpts from analysts' reports or news articles quoted within this work. Copyright © 2005 by Scott+Scott, LLC. Scott+Scott, LLC will vigorously defend all of their rights to this writing/publication. All rights reserved – including the right to reproduce in whole or in part in any form. Any reproduction in any form by anyone of the material contained herein without the permission of Scott+Scott, LLC is prohibited.

Plaintiff, individually and on behalf of all other persons similarly situated, by plaintiff's undersigned attorneys, for plaintiff's complaint against defendants, alleges the following based upon personal knowledge as to plaintiff and plaintiff's own acts, and upon information and belief as to all other matters, based on, inter alia, the investigation conducted by and through plaintiff's attorneys, which included, amongst other things, a review of the defendants' press releases, Securities and Exchange Commission ("SEC") filings by Guidant Corp. ("Guidant" or the "Company"), communications to the Company from the US Food and Drug Administration ("FDA") and media reports about the Company. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### **NATURE OF THE CASE**

1. This is a securities class action on behalf of plaintiff and all other persons or entities, except for defendants, who purchased or otherwise acquired Guidant securities ("the "Class") during the period December 15, 2004 and through June 17, 2005, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

#### **JURISDICTION AND VENUE**

2. Jurisdiction is conferred by §27 of the 1934 Act. The claims asserted herein arise under §10(b) and 20(a) of the 1934 Act and Rule 10b-5.

3. Venue is proper in this District pursuant to §27 of the 1934 Act. The corporate headquarters of Guidant are located in the District.

4. In connection with the acts and conduct alleged herein, defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the United States mails and the facilities of the national securities exchanges.

## PARTIES

5. Plaintiff, Moussa Yeroushalmi as set forth in the accompanying certification and incorporated by reference herein, purchased shares of Guidant stock at artificially inflated prices during the Class Period and was damaged thereby.

6. Defendant Guidant provides therapeutic medical solutions for customers, patients, and healthcare systems worldwide. The company develops, manufactures, and markets products that focus on the treatment of cardiac arrhythmias, heart failure, and coronary and peripheral disease, including Guidant's implantable defibrillator systems, used to detect and treat abnormally fast heart rhythms that could result in sudden cardiac death. Guidant maintains its corporate and administrative offices, where the Company's day-to-day business activities are conducted, at 111 Monument Circle, 29th Floor, Indianapolis, IN 46204-5129.

7. Defendant Ronald W. Dollens ("Dollens") was Chief Executive Officer, President and Director of Guidant. During the Class Period, defendant Dollens sold approximately \$20.1 million worth of his Guidant stock. Dollens is a member of Guidant's Compliance Committee, which is charged with reviewing Guidant's regulatory compliance and internal control procedures and with overseeing compliance with Guidant's Code of Business Conduct, and on its Governance Committee. As such, Dollens was directly responsible for oversight of Guidant's compliance with state and federal laws and FDA regulations and with setting in place proper corporate governance policies and mechanisms.

8. Defendant Guido J. Neels ("Neels") was Chief Operating Officer ("COO") of Guidant. During the Class Period, defendant Neels sold approximately \$4.3 million worth of his Guidant stock.

9. Defendant Keith E. Brauer ("Brauer") was Vice President and CFO of Guidant. During the Class Period, defendant Brauer sold approximately \$3.6 million worth of his Guidant stock.

10. Defendant Beverly H. Lorell (“Lorell”) was Vice President and Chief Medical Officer of Guidant. During the Class Period, defendant Lorell sold approximately \$3.3 million worth of her Guidant stock.

11. Defendant Ronald N. Spaulding (“Spaulding”) was President of Guidant’s Europe, Middle East, Africa and Canada (“EMEAC”) division. During the Class Period, defendant Spaulding sold approximately \$4.2 million worth of his Guidant stock.

12. Defendant William F. McConnell Jr. (“McConnell”) was Vice President and CIO of Guidant. During the Class Period, defendant McConnell sold approximately \$3.7 million worth of his Guidant stock.

13. The individuals named as defendants in ¶¶7-12 are referred to herein as the “Individual Defendants.” The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Guidant quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each “group-published” information, the result of the collective actions of the Individual Defendants.

#### **SCIENTER**

14. In addition to the above-described involvement, each Individual Defendant had knowledge of Guidant’s problems. Each defendant was motivated to

conceal such problems. Defendant Brauer, serving as CFO, provided for financial reporting and communications with the market. Communications with the market, including conference calls, as well as internal reports showing Guidant's forecasted and actual growth were prepared under his direction. Defendant Dollens, serving as CEO also provided for communications with the market, including conference calls, as well as reports on Company operations, financing and press releases issued by the Company. Defendants Neels, as Chief Operating Officer and Lorrell, as Chief Medical Officer had joint responsibility for communications. Each Individual Defendant sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. Each individual defendant also owed a duty to the Company and its shareholders not to trade on inside information.

#### **FRAUDULENT SCHEME AND COURSE OF BUSINESS**

15. Each defendant is liable for (a) making false statements, *or* (b) failing to disclose adverse facts known to him about Guidant. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Guidant publicly traded securities was a success, as it (a) deceived the investing public regarding Guidant's prospects and business; (b) artificially inflated the prices of Guidant's publicly traded securities; (c) allowed defendants to negotiate a lucrative \$25.4 billion merger deal with Johnson and Johnson; (d) allowed defendants to sell \$39.5 million of their own shares at inflated prices; and (e) caused plaintiff and other members of the Class to purchase Guidant's publicly traded securities at inflated prices.

#### **OVERVIEW OF THE CASE**

16. Defendant Guidant provides therapeutic medical solutions for customers, patients, and healthcare systems worldwide. The company develops, manufactures, and markets products that focus on the treatment of cardiac arrhythmias, heart failure, and

coronary and peripheral disease, including implantable defibrillator systems, implantable pacemaker systems, coronary stent systems, angioplasty systems, cardiac surgery systems, and Peripheral systems. Guidant's implantable defibrillator systems are used to detect and treat abnormally fast heart rhythms that could result in sudden cardiac death.

17. On June 12, 2003, Guidant announced a settlement with the US Department of Justice ("DOJ") relating its Ancure stent graft system, which was marketed as a safer and less invasive alternative treatment for abdominal aortic aneurysm. The Ancure investigation resulted in a record payment of \$43.4 million, an additional \$49 million civil settlement to the government and an agreement by the Company to plead guilty to 10 felony counts.

18. Unbeknownst to investors, from a time prior to the Class Period and the Ancure settlement with the DOJ, defendants engaged in the manufacture and distribution of defective implantable defibrillators. Amongst the various defects known to the Company was the "short circuit" defect, causing the implantable defibrillator to stop functioning for a 24-hour period, then resume function but erasing the memory so that the malfunction is not detectable by the physician or the patient. As such, the malfunction is only detectable by a physician in the rare event that the proper function of the defibrillator is being tested. Despite defendants' felony convictions and "remedial actions" in connection with the Ancure debacle, defendants had concealed from the public and physicians the longstanding life-threatening defects known to exist in Guidant's implantable defibrillators.

19. The Class Period begins on December 15, 2004, whereupon Guidant management entered into a \$24.5 billion merger deal with Johnson and Johnson. While the Company pointed to its defibrillator business as a key component of that deal, it concealed from investors significant unaddressed product defect and liability issues of the Company's implantable defibrillator product lines. Although life-threatening, defendants knew or consciously disregarded the fact that these mechanical problems were difficult to

characterize and observe in implanted patients, making unlikely that any temporary physical disablement in patients would be attributed to device malfunction.

20. On June 17, 2005, FDA issued a nationwide recall notification, impacting Guidant's implantable defibrillators and cardiac resynchronization therapy defibrillators. Within that notification, FDA advised the public that the malfunction of Guidant's devices could lead to a serious, life-threatening event for a patient. Moreover, FDA now advised that there had been two reported deaths suspected to be associated with this malfunction. FDA advised patients to take the following steps to keep their regular doctor appointments, to immediately report any electrical shock from the devices to their doctors. Finally, FDA advised patients to immediately contact their doctors or go to the nearest emergency room, should an audible "beeping" result, since this may mean that the defibrillator device is damaged. Finally, FDA advised that if you are a physician or a patient who has experienced a problem with any of these defibrillators, please send a report to FDA's MedWatch program and to Guidant. See <http://www.fda.gov/medwatch/> for filing information, information for physicians at [www.guidant.com](http://www.guidant.com), call 1-800-FDA-1088 (1-800-332-1088) or contact Guidant at 1-866-GUIDANT (1-866-484-3268).

21. On the shocking news, the Company's shares fell \$3.36, losing 4.5% percent of their value over the two trading days following the FDA recall, closing at \$70.33, on a combined volume of over 25 million shares. As a result, Guidant investors lost over \$1.09 billion in the value of their shares as a result of the surprise announcement of the FDA recall.

22. During the Class Period, defendants knew and concealed:

- (a) serious and alarming health issues encountered by patients caused by the malfunctioning and defective nature of the Company's defective devices;
- (b) how the way in which the Company orchestrated its product design, manufacturing, quality, consumer complaint and corporate compliance functions prevented product failure investigations and other corrective actions from triggering

responsible corporate actions, especially the timely recall of the Company's defective products;

(c) its failure to achieve affirmative corrective and preventative actions consistent with the spirit and letter of the Company's own corporate integrity guidelines, even after the Company had entered into a "corporate integrity agreement" with the Office of the Inspector General of the U.S. Department of Health and Human Services;

(d) the overwhelming threat to the deal defendants had forged with Johnson and Johnson for the sale of Guidant, including the threat to the ability of insiders to profit as a result of stock sales during the Class Period;

(e) the lack and insufficiency of communications to healthcare providers and patients regarding the defective nature of the Company's defibrillator products, even when adequate communications were essential to protect the lives of its implant patients; and

(f) the troubling decision to await overwhelming negative media accounts before taking affirmative actions regarding the Company's defibrillator products.

**BACKGROUND AND DEFENDANTS'**  
**PRE-CLASS STATEMENTS**

23. Guidant's principal business is the development, manufacturing and marketing of products and services that enable less-invasive treatments for cardiac and vascular patients including stent systems, implantable defibrillator systems, implantable pacemaker systems, implantable cardiac resynchronization therapy, products for the treatment of abdominal aortic aneurysms, products to perform cardiac surgery procedures and intravascular radiotherapy systems for artery disease.

## **The Ancure Debacle**

24. Defendants are required by the Safe Medical Devices Act of 1990 to report to the FDA within 30 days whenever they received or otherwise became aware of information from any source that reasonably suggested that its medical device products (i) may have caused or contributed to a death or serious injury; or (ii) had malfunctioned and the device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. These reports are known as Medical Device Reports (“MDRs”). The FDA makes MDRs available to physicians and other members of the public so that they can be aware of recurring malfunctions and other risks concerning medical devices. Pursuant to federal regulation, submission of an MDR does not constitute an admission by a manufacturer that a device caused or contributed to the event that is reported.

25. Pursuant to federal law, a medical device causes or contributes to a death or serious injury whenever a death or serious injury was, or may have been, attributed to a medical device, or a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of failure, malfunction, improper or inadequate design, manufacture, labeling, or user error.

26. Pursuant to the relevant federal law, a patient undergoing a surgical procedure using defendants’ medical device products suffered a serious injury when he or she (i) experienced an injury that was life-threatening; (ii) experienced an injury or an illness that resulted in permanent impairment of a body function or permanent damage to body structure; or (iii) experienced an injury that required medical or surgical intervention to preclude permanent impairment of a body function or permanent damage

to a body structure. Evidence of actual causation is not required for there to be an obligation to file an MDR report.

27. It is a matter of public record that defendants engaged in criminal acts associated with their medical device development and marketing activities, resulting in felony convictions and fines. On June 12, 2003, Guidant announced a settlement with the Department of Justice relating its Ancure stent graft system, which was marketed as a safer and less invasive alternative treatment for abdominal aortic aneurysm. The Ancure investigation resulted in a record payment of \$43.4 million, an additional \$49 million civil settlement to the government and an agreement by the Company to plead guilty to 10 felony counts. The press release stated:

**EndoVascular Technologies Enters into Settlement with U.S. Department of Justice; No Risk to Patients Implanted with ANCURE ENDOGRAFT System**

EndoVascular Technologies, Inc. (EVT), a subsidiary of Guidant Corporation, today announced that it has entered into a settlement agreement with the U.S. Department of Justice into matters relating to the company's ANCURE® ENDOGRAFT® System for the treatment of abdominal aortic aneurysms (AAA).

Under the terms of the agreement, EVT has agreed to make a payment of \$43.4 million and an additional \$49 million civil settlement to the government. EVT has also agreed to plead guilty to 10 felony counts, including nine for shipping misbranded products and one count of a former employee making false statements to the government. The expenses associated with this settlement were recorded in prior periods.

Following the company's voluntary recall of the product in March 2001, EVT implemented thorough corrective actions to address certain regulatory compliance deficiencies. The product was reintroduced to the market following Food and Drug Administration approval in August 2001. The issues outlined in the plea agreement pertain only to the delivery system of the ANCURE device prior to the company's voluntary recall, and do not relate to the ANCURE graft once it has been implanted. No patient with the ANCURE ENDOGRAFT implant is at risk as a result of this matter, and the implant continues to demonstrate excellent long-term clinical results. More than 18,000 patients worldwide have been implanted with the ANCURE ENDOGRAFT System.

While the settlement agreement includes a civil payment, the company remains in discussions with the Office of the Inspector General

of the U.S. Department of Health and Human Services (HHS) concerning the nature and scope of any potential agreement.

28. So egregious was defendants' conduct in connection with Ancure that FDA found it necessary to formalize an agreement for Guidant corporate compliance, know as the "Corporate Integrity Agreement."<sup>1</sup> The agreement, which is linked to its "Guidant Code of Business Conduct" webpage ("the Code"), which provides a rigorous restatement and imposition of best quality compliance practices that can be adopted pursuant to law and FDA regulations, *is material to the extent that it is used to support defendants' assertions of its own definition of "corporate integrity."*<sup>2</sup>

29. Specifically, defendant Dollens "codified" the Company's definition of "corporate integrity" as "[c]ontinued honest and ethical business conduct [that] will earn Guidant the trust of customers, patients, suppliers, investors, regulators, and fellow employees, while sustaining our long-term commitment to our shareholders." Defendants' Code goes further, to define a webpage entitled "Dedication to Quality," which begins with the acknowledgement that, "[I]ives depend on the consistent delivery of quality products and services from Guidant. It is our responsibility to keep this in the forefront of our minds as we perform our duties each day. Superior quality is the key to our success, and anything less than our best is unacceptable."<sup>3</sup>

### **Guidant's Defective Implantable Ventak Prizm Defibrillators**

30. Despite defendants' comforting assertions related to "corporate integrity" in the wake of the Ancure debacle, it is alleged in a recently filed product liability

---

<sup>1</sup> See: [http://www.guidant.com/news/300/web\\_release/nr\\_000392.shtml](http://www.guidant.com/news/300/web_release/nr_000392.shtml), last accessed on June 20, 2005.

<sup>2</sup> See: <http://www.guidant.com/about/employee.shtml>, last accessed on June 20, 2005.

<sup>3</sup> See [http://www.guidant.com/about/employee\\_6.shtml](http://www.guidant.com/about/employee_6.shtml), last accessed on June 20, 2005.

complaint (the Brennan complaint) against Guidant that thousands of its implanted defibrillator devices have failed to operate in a safe and continuous manner, causing serious medical problems and, in certain patients, catastrophic injuries and deaths.<sup>4</sup> The Brennan complaint alleges, amongst other things, that defendants committed outright fraud and intentionally concealed material facts, as they knowingly marketed their defective defibrillator products.

31. Specifically, beginning as early as 1994, Guidant designed, manufactured and distributed pacemaker/defibrillator combinations, including the Ventak Prizm 2 VR/DR, models 1860/1861, the Ventak Prizm VR/DR, models 1850/1851/1855/1856, the Ventak Prizm VR/DR HE, models 1852/1853, the Ventak Mini IV, models 1790/1793/1796 and the Ventak Mini III HE, model 1789.

32. Mr. Brennan's complaint alleges that defendants' Ventak Prizm implantable defibrillators *are uniformly defective*, in that they short circuit, causing the implantable defibrillator to stop functioning for a 24 hour period, then resume function *but erasing the memory so that the malfunction is not detectable by the physician or the patient*. As such, the malfunction is only detectable by a physician in the rare event that the proper function of the defibrillator is being tested.

33. In fact, at least one patient has died as a result of the defective Ventak Prizm implantable defibrillator, because the implantable defibrillator short circuited and

---

<sup>4</sup> The product liability complaint of Mr. John Brennan, ("the Brennan complaint") himself an implanted Ventak Prizm patient, was filed and docketed as Civil Docket No. 1:05-cv-00827-DFH-TAB, in the U.S. District Court, Southern District of Indiana on June 1, 2005. The complaint relies in part on the media reports typified by that published in the May 24<sup>th</sup> edition of the New York Times, in an article entitled, "Maker of Heart Device Kept Flaw From Doctors". See ¶46. Mr. Brennan seeks class action certification, against Guidant and its subsidiary, Guidant Sales Corporation.

failed to function, failing to restore the patient's heart to a normal cardiac rhythm.<sup>5</sup> As a result of his concerns and fears founded upon the defective nature of this medical device, Mr. Brennan states in his complaint that his implanted Ventak Prizm defibrillator is "like having a grenade with the pin pulled in his chest".

34. The Brennan complaint further alleges that the underlying problem associated with several recalls during the period 1998-2001, covering 13,000 Ventak Prizm defibrillators was the same as the current problem with all of the Ventak Prizm implantable defibrillators. Specifically, the defibrillator itself short-circuits and fails to function for a 24 hour period, erasing the memory of the event, and erasing the memory built into the device so that any history of the patient's cardiac arrhythmias is not recorded or maintained, making care provisions for the implanted Ventak Prizm defibrillator patient much more difficult.<sup>6</sup>

35. Defendants note on their website that the Ventak Prizm is in fact designed to store programmed device parameters necessary to its proper function, as well as to record the patient's vital historical information, relating to cardiac arrhythmias and other events, as stated in part:<sup>7</sup>

---

<sup>5</sup> Consistent with the allegations contained within the Brennan product liability complaint, there is at least one confirmed report of patient death attributable to the Ventak Prizm. Within this report, Guidant stated "It was further indicated that the event may possibly be related to the icd". See the FDA Adverse Event Report appearing at: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI\\_ID=296519](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI_ID=296519), last accessed on June 20, 2005.

<sup>6</sup> Consistent with the allegations contained within the Brennan product liability complaint, a recall notice for 13,833 Ventak Prizm defibrillators, related to a "rare interaction between the device and a specific memory component" is entered on FDA's Enforcement Report for August 8, 2001, appearing at: <http://www.fda.gov/bbs/topics/ENFORCE/2001/ENF00705.html>, last accessed on June 20, 2005.

<sup>7</sup> See: [http://www.guidant.com/products/ProductTemplates/CRM/Ventak\\_Prizm\\_2.shtml](http://www.guidant.com/products/ProductTemplates/CRM/Ventak_Prizm_2.shtml), last accessed on June 20, 2005.

## Therapy History

In addition to storing programmed device parameters, VENTAK PRIZM 2 models store the patient's therapy history. This therapy history is a record of the most recent arrhythmia episodes and includes the following:

- Graphic summary of arrhythmic episodes (VT, VF, SVT, atrial) with hot links to episodes of interest
- Up to 150 clinically significant (VT, VF, SVT, ATR, PMT) events in an arrhythmia logbook, including:
  - Date and time of episode
  - Episode type
  - Onset rate
  - Zone of therapy, therapy used, therapy diverted
  - Measured enhancement data
- Up to 1,024 annotated R-R/P-P intervals stored per episode
- Up to 19 minutes of annotated stored intracardiac electrograms from the atrial, ventricular, or shocking electrodes
- Detailed episode information including detection, therapy, and post-therapy redetection parameters
- Brady and tachy therapy counters

36. Thus, despite defendants' felony convictions and "remedial actions" in connection with the Ancure debacle, the Brennan product liability complaint states that Guidant had concealed from the public and physicians ***the longstanding life-threatening defect common to all of their Ventak Prizm implantable defibrillators, in that they all malfunction in the manner described.***

## Guidant's Other Defective Implantable Defibrillators

37. In addition to the defective nature of Guidant's Ventak Prizm defibrillators, Guidant knew from a time before the Class Period of life-threatening problems with other defibrillator models, including those sold under the Contak Renewal product line. In an FDA adverse events report dated April 23, 2004, the following account of the defective nature of a Contak Renewal defibrillator was reported, in pertinent part:

Adverse Event Report

GUIDANT CORP. CONTAK RENEWAL H135 ICD

back to search results

Model Number H135

Patient Outcome Required Intervention;

Event Description

Misprogrammed device--device implanted in 2003 with a factory set av delay of 110. The next day a guidant tech optimized the av delay to a setting of 60. Guidant uses a statistical database to arrive at a setting. ***During their phone call with guidant, the tech questioned the setting as potentially being too low. When they got off the phone, they told pt they had never had such a low setting and doubted it could be correct. They did not, however, relay their concerns to either pt's electrophysiologist or pt's cardiologist. Pt had no idea what the setting referred to and was unaware of the potential for harm.*** April to june pt suffered with heart failure so disabling as to disallow standing to shower and walking without a cane. Pt was advised by both the guidant rep and their electrophysiologist that pt's suffering was unquestionably the result of the misprogrammed setting. ***There is no doubt in pt's mind that had the guidant tech notified pt's electrophysiologist of their concerns about the av delay setting, it could have been addressed and corrected immediately.*** Two mos later the setting was re-optimized by echocardiogram to the correct setting of 140. Pt continues to feel tired and certainly did not revert to the level of health enjoyed prior to implant. Nights found pt on the sofa curled in the fetal position because pt felt very ill, knew something was quite wrong, but had no way of identifying the problems or resolving them. ***Pt was later to learn the device had a defective circuit board.*** Premature battery depletion: three mos later pt noted a consistent set of beeps occurring at a regular interval. ***Entering the er the following day, drs noted the battery depleted to the point of requiring replacement. Two days later the device was explanted and a new one implanted. The***

*defective device was returned to guidant for evaluation. Deffective circuit board: pt's electrophysiologist advised pt that guidant notified him that examination of the explanted device revealed defects in the circuit board.*

Brand Name CONTAK RENEWAL H135

Type of Device ICD

Manufacturer (Section D) GUIDANT CORP.

4100 hamline ave n.

st paul MN 55112 5798

Device Event Key 514944

MDR Report Key 525805

Event Key 499086

Report Number 525805

Device Sequence Number 1

Product Code LWS

Report Source Voluntary

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 04/23/2004

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? Yes

Device Operator Invalid Data

Device MODEL Number H135

Was Device Available For Evaluation? No Answer Provided

### **Lifestyle Issues For Individuals with Implanted Defibrillators**

38. Individuals with implanted defibrillators face a variety of lifestyle issues that must be carefully managed, even with the expectation that their defibrillator of the

highest quality, as indicated by cardiologists Mittal, Stein and Hamby, in their advice entitled "Living With An Implantable Defibrillator,"<sup>8</sup> which states in pertinent part:

#### Lifestyle considerations with ICDs

ICD patients are often given a card that provides basic information on the ICD as well as emergency instructions. This card should be kept on person at all times. In addition, patients should memorize their ICD make and model. ***Although mechanical problems are rare, this information will prepare patients in the event of an ICD recall by a manufacturer.***

Patients may want to wear a medical alert bracelet or necklace with information on their ICD and should inform all healthcare providers about the device, including dentists. Patients are also advised to avoid any activity that could result in impact to the ICD site, such as contact sports, and should never place a magnet near the site because it could interrupt the ICD's function.

\*\*\*

Stress management may be even more important for people with ICDs than it is in general. Many patients experience stress in relation to their ICD. Some say that the shocks it delivers, if necessary, are very painful, and some patients are anxious about ICD discharge or physical activity. Researchers have found that mental stress may cause instability in the heart's electrical signals for patients with ICDs. The heart's conduction system may be more sensitive to stress for these patients. If a patient is experiencing stress, whether connected to the ICD or for another cause, a physician may be able to direct them to a support group or a clinician who specialize in stress management.

39. Based on these lifestyle concerns, it is easy to understand why patients with implanted defibrillators would be gravely concerned once they would learn of information about the defective nature of their implants. Worse, these concerns would reasonably multiply when this information is first transmitted through media accounts of an active concealment, as opposed to communications orchestrated through legitimate

---

<sup>8</sup> This advice appears on the [www.heartcenteronline.com](http://www.heartcenteronline.com) website, on the webpage, at: <http://www.heartcenteronline.com/myheartdr/common/articles.cfm?Artid=597&startpage=2#>, last accessed on June 20, 2005.

regulatory and physician channels, intended to effectively deal with the serious life-threatening issues and substantial costs associated with these defective devices.

**DEFENDANTS' FALSE AND MISLEADING STATEMENTS**  
**MADE DURING THE CLASS PERIOD**

40. On December 15, 2004, the Company issued a press release entitled, "Johnson & Johnson and Guidant Announce Definitive Agreement Valued at \$23.9 Billion Based on \$76 per Share - Transaction will bring together cardiovascular expertise and technologies to benefit patients and physicians worldwide." The press release stated in part:

New Brunswick, N.J. and Indianapolis, Ind. — December 15, 2004 — Johnson & Johnson (NYSE: JNJ), the world's most comprehensive and broadly based manufacturer of health care products, and Guidant Corporation (NYSE: GDT), a world leader in the treatment of cardiac and vascular disease, today announced that they have entered into a definitive agreement whereby Johnson & Johnson will acquire Guidant for \$25.4 billion in fully diluted equity value.

Under the terms of the agreement, each share of Guidant common stock will be exchanged for \$30.40 in cash and \$45.60 in Johnson & Johnson common stock, provided the average Johnson & Johnson common stock price is between \$55.45 and \$67.09 during the 15-day trading period ending three days prior to the transaction closing. Each Guidant share exchanged would be converted into Johnson & Johnson common stock of not more than .8224 and not less than .6797 shares, plus \$30.40 in cash. The transaction has an estimated net acquisition cost of \$23.9 billion, as of the close of business on December 15, 2004, based upon Guidant's approximately 334 million fully diluted shares outstanding, net of estimated cash on hand at the time of closing.

The boards of directors of Johnson & Johnson and Guidant have given their respective approvals to the transaction, which is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act, the European Union merger control regulation, and other customary closing conditions. The agreement will require the approval of Guidant's shareholders.

Guidant and Cordis Corporation, a Johnson & Johnson Company, will become part of a newly created cardiovascular device unit within Johnson & Johnson. The newly created franchise will be named Guidant while the Cordis name will be retained for select businesses within the franchise. The franchise will be operated consistent with the Johnson &

Johnson operating principle of decentralized management, which provides for focused management and fosters an entrepreneurial culture. This business unit will report to Nicholas J. Valeriani, a member of the Johnson & Johnson Executive Committee.

“The combination of these businesses will enable us to bring innovative new therapies to patients and their physicians in this very important and fast growing therapeutic area,” said William C. Weldon, Chairman and Chief Executive Officer of Johnson & Johnson. “Bringing Guidant into the Johnson & Johnson family of companies builds on our history of strategic acquisitions and partnerships that provide a foundation for sustained leadership and growth.”

***Guidant business units include cardiac rhythm management (e.g. pacemakers and implantable cardioverter defibrillators), vascular intervention, cardiac surgery and endovascular solutions. These businesses will complement Johnson & Johnson’s products and services in cardiology and medical devices, as well as provide future benefits for patients and physicians as a result of collaboration with the Johnson & Johnson pharmaceuticals and diagnostics businesses.***

“This exciting new partnership opens a dynamic era of innovation and product development that will benefit millions of patients around the world,” said Ronald W. Dollens, President and Chief Executive Officer of Guidant. “We are pleased to be joining Johnson & Johnson, one of the world’s premier companies. We strongly believe that this exciting collaboration will benefit patients, customers, employees and shareholders.” Mr. Dollens has agreed to continue to serve as Chief Executive Officer of Guidant until the transaction has closed.

The cardiovascular segment continues to be one of the fastest growing areas in health care as populations in the United States and other countries age. As a combined entity, Guidant and Cordis will more effectively bring technologically based and innovative approaches to the treatment of cardiovascular diseases.

***This new organization will enable Johnson & Johnson to better address the needs of patients around the world who require treatment for heart failure and sudden cardiac death.*** This patient population continues to be significantly underserved. Additionally, Guidant’s technology platforms, such as implantable micro-electronics, could be applied to current and future Johnson & Johnson products as part of future efforts to create innovative and advanced technologies in other healthcare areas, such as the neuromodulation market.

In the interventional cardiology market, this business combination provides the capability to accelerate development of new technologically advanced products. This new business can utilize Cordis’ expertise, intellectual property and experience in drug development, coating technology and polymers. Together with Guidant’s strength in rapid and innovative development of stent platforms and delivery systems, the combined company will bring superior products to the market faster than either company could on its own.

Guidant Corporation pioneers lifesaving technology, giving an opportunity for better life today to millions of cardiac and vascular patients worldwide. The company, driven by a strong entrepreneurial culture of approximately 12,000 employees, develops, manufactures and markets a broad array of products and services that enable less invasive care for some of life's most threatening medical conditions. For more information visit [www.guidant.com](http://www.guidant.com).

Johnson & Johnson, with approximately 109,000 employees, is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical, and medical devices and diagnostics markets. Johnson & Johnson has more than 200 operating companies in 57 countries, selling products throughout the world. For more information visit [www.jnj.com](http://www.jnj.com).

Additional commentary regarding the financial impact will be discussed during the conference call noted below. Johnson & Johnson and Guidant will not be available for further comment until after the conference call has concluded.

41. The press release of December 15, 2004 was false and misleading for the following reasons. First, defendants knew that their implantable defibrillator product lines presented significant liability issues, given past and ongoing unaddressed issues related to substantial life-threatening defects related to the design and manufacture of these devices. Since these problems difficult to characterize and observe, those patients implanted with these defective devices were unlikely to attribute any temporary physical disablement to device malfunction. Specifically, the Company knowingly misrepresented the defective nature of its defibrillator products, to conceal the meaning and significance of:

(a) serious and alarming health issues encountered by patients caused by the malfunctioning and defective nature of the Company's defective devices;

(b) how the way in which the Company orchestrated its product design, manufacturing, quality, consumer complaint and corporate compliance functions prevented product failure investigations and other corrective actions from triggering responsible corporate actions, especially the timely recall of the Company's defective products;

(c) failure to achieve affirmative corrective and preventative actions consistent with the spirit and letter of the Company's own corporate integrity guidelines,

even after the Company had entered into a “corporate integrity agreement” with the Office of the Inspector General of the U.S. Department of Health and Human Services;

(d) lack and insufficiency of communications to healthcare providers and patients regarding the defective nature of the Company’s defibrillator products, even when adequate communications were essential to protect the lives of its implant patients; and

(e) the troubling decision to await overwhelming negative media accounts before taking affirmative actions regarding the Company’s defibrillator products.

42. Secondly, defendants knew that any revelations of the extent of the defective nature of its defibrillator products would put at risk the present and lucrative agreement whereby Johnson & Johnson would acquire the Company for \$25.4 billion in fully diluted equity value. As a result of the announcement of December 15, 2004, a record 36 million shares of Guidant stock were traded, locking in a modest 4.2% speculative appreciation in the price of the Company’s stock,<sup>9</sup> occurring as a result of rumors associated with the agreement. Despite this, the Company concealed its continued conscious and reckless disregard of the defective nature of its defibrillator products, including the enormous risks they presented to patients implanted with the devices.

43. On April 21, 2005, the Company issued a press release entitled, “Guidant Reports Record First Quarter Sales of \$953 Million - Company Completes Several Merger-Related Milestones During Quarter - Sales of products other than worldwide coronary stents were \$838 million, up 10 percent - Worldwide implantable defibrillator revenue of \$478 million, up 18 percent - Worldwide coronary stent revenue of \$115

---

<sup>9</sup> One of the first media accounts of the potential for a JNJ-Guidant deal was published in Tuesday, December 7, 2004 edition of the New York Times, in an article entitled, “Johnson Said To Be in Talks For Heart Device Maker”. On December 7, 2004, shares of Guidant’s stock rose 5.2%, to close at \$73.35, on volume of 23.3 million shares.

million, down 33 percent - Earnings per share from continuing operations of \$0.54, up 13 percent - Adjusted earnings per share from continuing operations of \$0.65, up 16 percent". The press release stated in part:

Guidant Corporation (NYSE: GDT), a world leader in the treatment of cardiac and vascular disease, today reported first quarter sales of \$953 million, representing sales growth of \$19 million or 2 percent versus the prior year. Foreign currency translations favorably impacted revenue by \$13 million. Net income for the quarter was \$162 million versus \$139 million in the first quarter of 2004, up 16 percent.

Please see the attached schedules and the Guidant website at [www.guidant.com/investors/reconciliations/](http://www.guidant.com/investors/reconciliations/) for additional information, including a reconciliation of special items, income statements and product sales summaries reclassified for discontinued operations.

#### Management Observations

Ronald W. Dollens, president and CEO of Guidant Corporation, commented, "Guidant's results this quarter reflect solid operating performance through continued financial discipline and strong revenue growth in implantable defibrillators and our emerging businesses. As planned, we are making timely progress toward the closing of the company's merger with Johnson & Johnson."

***Dollens continued, "As we look to the future, we expect strong growth in the implantable defibrillator market supported by expanded Medicare reimbursement, limited erosion in our coronary stent revenue, and increased contributions from our emerging businesses."***

#### First Quarter Financial Highlights:

Sales of products other than worldwide coronary stents represented 88 percent of total revenues and increased 10 percent versus the first quarter of 2004.

Worldwide implantable defibrillator sales increased 18 percent to \$478 million; U.S. implantable defibrillator sales were \$366 million.

Worldwide pacemaker sales declined 6 percent to \$168 million; U.S. pacemaker sales were \$95 million.

Worldwide coronary stent sales of \$115 million declined 33 percent versus the prior year and represented 12 percent of company sales; U.S. stent sales totaled \$57 million.

Worldwide angioplasty system sales declined 14 percent to \$100 million, reflecting the temporary unavailability of the company's leading dilatation catheter during the quarter.

Worldwide sales of cardiac surgery, biliary, peripheral and carotid systems (emerging businesses) grew 49 percent to \$92 million.

Gross margin was 76.4 percent compared to 75.8 percent in the first quarter of 2004.

The company reported first quarter income and earnings per share from continuing operations of \$177 million and \$0.54 compared to \$153 million and \$0.48 in the first quarter of 2004. Income from continuing operations in the current quarter includes an after tax impairment charge of \$38 million, or \$0.11 per share, related to the write-down of assets associated with declining demand and future outlook for the FX miniRAIL Dilatation Catheter. Adjusted income and earnings per share from continuing operations, excluding special items, were \$215 million and \$0.65 compared to \$178 million and \$0.56 in the first quarter of 2004, up 20 and 16 percent, respectively. All results include merger-related expenses.

#### Merger Update

As previously announced on December 15, 2004, Guidant and Johnson & Johnson entered into a definitive agreement whereby Johnson & Johnson will acquire Guidant for \$76 per share or \$25.4 billion in fully diluted equity value.

Merger related milestones in the quarter included U.S. and European regulatory filings as well as providing proxy materials to company shareholders in connection with the special meeting to approve the merger on April 27, 2005. If approved by Guidant shareholders, the transaction will remain subject to receipt of regulatory approvals as well as other customary closing conditions. As expected, the company anticipates entering the second phase of European Commission review of the transaction this week. As previously announced, Johnson & Johnson and the company received a request for additional information (second request) from the Federal Trade Commission on February 18, 2005 and are in the process of responding.

The announced acquisition price of \$76 per share reflects \$30.40 in cash and \$45.60 in Johnson & Johnson common stock per share, provided the volume weighted average trading price of Johnson & Johnson common stock price is between \$55.45 and \$67.09 during the 15-day trading period ending three days prior to the transaction closing. Outside this range, each Guidant share exchanged will be converted into a fixed number of shares of Johnson & Johnson common stock equal to .8224 shares (at \$55.45 or below) or .6797 shares (at \$67.09 or above), plus \$30.40 in cash. On April 20, the closing price for common shares of Johnson & Johnson was \$68.10.

44. The press release of April 21, 2005 was false and misleading for the following reasons. First, defendant Dollens knew that the Company's implantable defibrillator product lines presented significant liability issues, given past and ongoing

unaddressed issues related to substantial life-threatening defects related to the design and manufacture of these devices. Dollens already knew that his expectation of “strong growth in the implantable defibrillator market supported by expanded Medicare reimbursement” did not factor in the inevitable and extraordinary product recall costs associated with the defective devices.

45. In making his statements of April 21, 2005, Dollens knew or consciously disregarded the fact that the defective nature of Ventak Prizm defibrillators was difficult to characterize and observe. As such, the defective nature of the Ventak Prizm defibrillators was easy to conceal from the medical community, patients and the investment community. Moreover, those patients implanted with the Company’s defective devices were unlikely to attribute any temporary physical disablement to device malfunction. Specifically, Dollens knowingly misrepresented prospects for the sales and marketing of the Company’s defibrillator products, to conceal the meaning and significance of:

(a) serious and alarming health issues encountered by patients caused by the malfunctioning and defective nature of the Company’s defective devices;

(b) how the way in which the Company orchestrated its product design, manufacturing, quality, consumer complaint and corporate compliance functions prevented product failure investigations and other corrective actions from triggering responsible corporate actions, especially the timely recall of the Company’s defective products;

(c) failure to achieve affirmative corrective and preventative actions consistent with the spirit and letter of the Company’s own corporate integrity guidelines, even after the Company had entered into a “corporate integrity agreement” with the Office of the Inspector General of the U.S. Department of Health and Human Services;

(d) lack and insufficiency of communications to healthcare providers and patients regarding the defective nature of the Company's defibrillator products, even when adequate communications were essential to protect the lives of its implant patients;

(e) the overwhelming threat to the deal defendants had forged with JNJ for the sale of Guidant, including the threat to the ability of insiders to profit as a result of stock sales during the Class Period; and

(f) the troubling decision to await overwhelming negative media accounts before taking affirmative actions regarding the Company's defibrillator products.

### **The Scheme Unravels**

46. On May 24, 2005, the New York Times published an article entitled, "Maker of Heart Device Kept Flaw From Doctors". The news article stated in part:

A medical device maker, the Guidant Corporation, did not tell doctors or patients for three years that a unit implanted in an estimated 24,000 people that is designed to shock a faltering heart contains a flaw that has caused a small number of those units to short-circuit and malfunction.

The matter has come to light after the death of a 21-year-old college student from Minnesota, Joshua Oukrop, with a genetic heart disease. Guidant acknowledges that his device, known as a defibrillator, short-circuited. The young man was in Moab, Utah, on a spring break bicycling trip in March with his girlfriend when he complained of fatigue. He then fell to the ground and died of cardiac arrest.

Guidant subsequently told his doctors that it was aware of 25 other cases in which the defibrillator, a Ventak Prizm 2 Model 1861, had been affected by the same flaw. Guidant said it had changed its manufacturing processes three years ago to fix the problem. The physicians say that had they known earlier, they would have replaced the unit in their patient because he was at high risk of sudden death. His death is the only one known.

A defibrillator is surgically implanted in the chest under the skin. It sends out an electrical charge to try to shock a chaotically beating heart back into normal rhythm.

In interviews in recent days, a top Guidant executive, Dr. Joseph M. Smith, said that the company had not seen a compelling reason to issue an alert to physicians about the defibrillators because the failure rate was very low and replacing the devices might pose greater patient risks.

But late yesterday, when told that The New York Times was preparing an article about the device, the company issued an advisory to doctors about it. Guidant is recommending that the unit not be replaced because of the electrical problem.

The episode highlights an important issue: Doctors and patients are not always told when a medical device maker has data indicating that its product has a flaw that, while rare, poses potential dangers. Also, companies are not required to report immediately all safety modifications to the Food and Drug Administration.

In February another defibrillator maker, Medtronic Inc., notified doctors that the battery used in one of its models was draining far faster than expected. At that time, the company had received nine reports among 87,000 affected units, an incidence of failure of 0.01 percent, which is lower than the figure for the affected Guidant defibrillators, which is 0.07 percent, based on 37,000 units manufactured before the modification. The Medtronic devices have not been associated with a death or an injury. However, in its advisory to doctors, Medtronic said its testing indicated that the problem could worsen over time and affect 0.2 percent to 1.5 percent of its units. The Guidant problem, Dr. Smith said, has remained constant over time.

One cardiologist said that Medtronic officials told him that physicians had replaced over 11,000 of the devices; a company spokeswoman said the company planned to release data today.

Dr. William H. Maisel, who has studied how doctors respond to device alerts, said that companies considering an alert face competing concerns over the cost of replacement versus harm to their reputations. As a result, Dr. Maisel, a cardiologist at Brigham and Women's Hospital in Boston, said there was the potential for a "huge conflict of interest."

The Guidant executive, Dr. Smith, who is the chief medical officer of Guidant's cardiac rhythm management division, rejected any suggestion that financial or liability concerns had influenced the company's decision.

He said that the Model 1861 was among the most reliable defibrillators available, adding that Guidant believed that it would cause more harm than good by publicizing the issue because replacement defibrillators might not perform as well and because surgery also posed risks. While fatalities during defibrillator implantation are extremely rare, the procedure poses an infection rate of about 1 percent.

"We choose to extraordinarily communicate when we have a product that does not live up to our expectations," Dr. Smith said. He added that issues that could improve patient outcomes would also warrant an alert to doctors. "In this case, neither condition was met," he said.

Guidant, which is based in Indianapolis, is one of the largest makers of medical devices, with \$3.8 billion in sales last year, almost half of that coming from implantable defibrillators. In December, Johnson & Johnson announced it planned to buy Guidant in a deal worth \$25.4 billion.

Defibrillators need to be replaced every five or six years because their batteries drain.

Implanted defibrillators are among the fastest-growing group of medical devices; this year alone, more than 200,000 patients are expected to get one. In 2001, Vice President Dick Cheney received one made by Medtronic. A defibrillator can cost up to \$25,000 and hospital and doctor costs can run another \$15,000.

In interviews, doctors in Minnesota who treated Joshua Oukrop said they were angered by Guidant's decision not to notify physicians because they said the company had received enough reports about the flaw to establish a pattern and because high-risk patients could suffer potentially catastrophic results.

Dr. Barry J. Maron of Abbott Northwestern Hospital in Minneapolis said that Dr. Smith was simply using numbers to support his stance.

"It is a statistical argument that has little to do with real people," Dr. Maron said. He also said that the numbers reported to Guidant might understate the situation because product problems could go undetected or might not be reported.

The short circuit can occur when the device builds a charge to deliver the type of high-energy shock needed in emergency situations. In three cases, when doctors intentionally induced abnormal heart rhythms during routine checkups, the Guidant device failed to work, forcing doctors to rescue those patients by jolting them with the type of external defibrillator used in emergency rooms.

All the electrical malfunctions involving the particular model occurred in units produced during a two-year period before mid-2002, when the company fixed the flaw. The problem has not happened in any devices made since.

F.D.A. regulations permit companies to inform the agency in two different ways about a manufacturing modification to improve safety, either while the company is making it or later, when a device maker files its annual report with the agency.

A Guidant spokeswoman, Annette Ruzicka, said that it reported the November 2002 change as part of an annual report submitted to the F.D.A. in August 2003.

As reports of individual problems came in, Guidant filed them with the F.D.A.

Dr. Robert G. Hauser, also of Abbott Northwestern Hospital in Minneapolis, said he recently started alerting cardiologists about the Guidant unit through a database he maintains that collects data about defibrillator and pacemaker failures.

He and Dr. Maron have also submitted an article about their patient's case to a medical journal. One of those contacted, Dr. David S. Cannom, who sits on Guidant's board of outside medical advisers, said in an interview that he believed that doctors should have all the facts.

He said that while risks posed by the device were small enough to argue against replacement in many patients, that calculus could shift substantially for high-risk ones.

"At the end of the day, you have to come down on the side of full disclosure," said Dr. Cannom, the director of cardiology at Good Samaritan Hospital in Los Angeles.

Over all, implanted defibrillators have a good record of reliability and are credited with saving countless lives, but the Minnesota case appears to illustrate the consequences that can result when company officials decide not to directly alert doctors to a problem, even for reasons that they believe are justified. Joshua Oukrop suffered from a relatively common genetic disease, hypertrophic cardiomyopathy, which can cause abrupt cardiac arrest.

One of his doctors, Dr. Maron, is an expert on the condition and a leading proponent of using implanted defibrillators to reduce deaths caused by the disease. Dr. Hauser, who was also involved in the young man's treatment, is a former chief executive of Cardiac Pacemakers Inc., one of five companies that was spun off by Eli Lilly in 1994 to form Guidant.

Joshua's father, Lee Oukrop, said that when his son was 17, he began fainting and falling down at marching band practice or while playing softball. The heart disease had previously been diagnosed in an older son, Jacob, so Mr. Oukrop took Joshua to see Dr. Maron in 2001. The physician determined that the teenager's condition was severe, and an implant was soon performed.

Mr. Oukrop, a millwright who lives in Grand Rapids, Minn., a small town about 80 miles west of Duluth, said that Dr. Maron had said "that this was the fix and that Josh could live with this."

For over three years, Mr. Oukrop said, his son's life was normal. He attended college, where he was studying to be a teacher, and was an outdoor enthusiast who hiked, snowboarded and bicycled. Like other defibrillator users, he saw his doctors every three months so they could check the device.

When Guidant inspected the device after Joshua's death, it found that the unit had short-circuited when it was charging up. Because the short circuit also destroyed the device's memory, it is not possible to know

whether the failure occurred while Joshua Oukrop was in cardiac arrest or at some other point.

"There was evidence of a device malfunction," said Dr. Smith, the Guidant executive.

After hearing a presentation a few weeks ago by Dr. Smith about the device, Dr. Maron, the genetic heart disease expert, said he asked what Guidant planned to tell doctors. "The answer was nothing," Dr. Maron said.

Dr. Smith, the Guidant executive, said the overall reliability rate of the Prizm 2 model exceeded company specifications both before and after the wiring fix.

So far, Dr. Maron and Dr. Hauser have notified dozens of their patients who got the Guidant unit to discuss possibly replacing it.

Dr. Maron said that now that the physicians were aware of the problem they had to consider, besides patient safety, their own responsibilities and potential liability.

Last week, Lee Oukrop, who has the same genetic heart disease as his sons and had the same Guidant device as Joshua, underwent a replacement procedure. He also said he was likely to hire a lawyer soon.

"Whoever made this decision at Guidant, I pray he doesn't have a son who this happens to," Mr. Oukrop said.

47. The press release of May 24, 2005 provided investors with an early indication of a potential threat to the deal Guidant had with Johnson and Johnson, based on the previously undisclosed defects associated with the Company's Ventak Prizm defibrillators. The news story had arguably painted Guidant as having caused the death of Joshua Oukrop, a 21-year-old college student from Minnesota. However, it had hardly placed a dent in the Company's stock price, since it stated that Guidant had told the Times that FDA was well-informed of the issues and had justified its unwillingness to share its product defect knowledge with the medical community. Moreover, the article failed to provide hard numbers or facts regarding the nature or extent of defective nature of defendants' defective defibrillator products. Without this information, investors were unable to comprehend the significance and extent of defendants' concealment or to make an informed judgment, regarding the potential financial impact of the serious and

alarming safety issues that resulted from the defective nature of the Company's defibrillator products.

48. Then, on June 17, 2005, FDA issued a press release entitled, "FDA Issues Nationwide Notification of Recall of Certain Guidant Implantable Defibrillators and Cardiac Resynchronization Therapy Defibrillators". The press release stated in part:

FDA is notifying health care providers and patients that the Guidant Corporation is recalling certain of its implantable defibrillators and cardiac resynchronization therapy defibrillators. These devices can develop an internal short circuit without warning, resulting in failure to deliver a shock when needed.

The devices affected by this notification are:

PRIZM 2 DR, Model 1861, manufactured on or before April 16, 2002

CONTAK RENEWAL, Model H135, manufactured on or before August 26, 2004

CONTAK RENEWAL 2, Model H155, manufactured on or before August 26, 2004

The devices are surgically implanted in persons who have a type of heart disease that creates the risk of a life-threatening heart arrhythmia (abnormal rhythm). The devices deliver an electrical shock to the heart to restore normal heart rhythm. The PRIZM 2 and RENEWAL devices are subject to different failures, resulting in the devices' inability to deliver an electrical shock during episodes of arrhythmia -- which could lead to a serious, life-threatening event for a patient. There have been two deaths reported to FDA suspected to be associated with this malfunction.

"FDA's first priority is patient safety," said Daniel Schultz, MD, Director of FDA's Center for Devices and Radiological Health. "We want to ensure that all patients who may be affected by this problem are notified and seek appropriate medical advice from their physicians."

FDA is not making a recommendation on whether individual patients who have one of the Guidant devices should have it removed and replaced. This is a decision that should be made by a patient in consultation with his or her physician, based on the specific medical situation of the patient. Removal and replacement of the device may pose some risk, so it is important that patients and physicians carefully discuss this matter before making a decision.

FDA advises patients to take the following steps:

If you have not already been notified, contact your doctor to determine if you have an affected PRIZM 2, CONTAK RENEWAL, or CONTAK RENEWAL 2 device.

Continue to keep your regular doctor appointments.

If you feel an electrical shock from your device, immediately contact your doctor.

If there is an audible "beeping" from your CONTAK RENEWAL or RENEWAL 2 device, immediately contact your doctor or go to the nearest emergency room. Beeping may mean that your defibrillator is damaged.

Guidant also recently informed FDA that it is recalling another set of defibrillator devices called PRIZM AVT, VITALITY AVT, RENEWAL 3 AVT and RENEWAL 4 AVT. The company has said the devices are subject to a memory error, which may affect device performance. Currently, FDA is evaluating this information.

If you are a physician or a patient who has experienced a problem with any of these defibrillators, please send a report to FDA's MedWatch program and to Guidant. See <http://www.fda.gov/medwatch/> for filing information or call 1-800-FDA-1088 (1-800-332-1088).

Guidant will be posting information for physicians on its web site at [www.guidant.com](http://www.guidant.com). If you have further questions, you may contact Guidant at 1-866-GUIDANT (1-866-484-3268).

49. The FDA recall announcement of June 17, 2005 ended the nearly three weeks of uncertainty that began with the news of the troubling death of Joshua Oukrop, as reported in the Times article of May 24, 2005. On the shocking news, the Company's shares fell \$3.36, losing 4.5% percent of their value over the two trading days following the FDA recall, closing at \$70.33, on a combined volume of over 25 million shares. As a result, Guidant investors lost over \$1.09 billion in the value of their shares as a result of the surprise announcement of the FDA recall. The timing and magnitude of the Guidant stock price decline negates any inference that the loss suffered by plaintiff and other class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the defendants' fraudulent conduct.

50. Following the close of the markets on June 20, 2004, Reuters published a news article entitled, "J&J unlikely to drop out of Guidant deal--sources". The article,

which pointed to the potential for renegotiation of the Guidant deal, as well as defibrillator recall costs, estimated from well under \$100 million to as much as \$225 million, stated in part:

CHICAGO, June 20 (Reuters) - Johnson & Johnson (JNJ.N: Quote, Profile, Research) is evaluating all of its options in the planned acquisition of cardiovascular device maker Guidant Corp. (GDT.N: Quote, Profile, Research) but is unlikely to walk away from the \$25.4 billion deal, sources familiar with the situation said Monday.

\*\*\*

Johnson & Johnson could require Guidant to set aside some funds to cover costs associated with the recall, the sources, who asked not to be named, told Reuters.

J&J could also decide to renegotiate the price of the deal, but at the moment, the financial impact of the recall appears manageable, the sources said.

\*\*\*

Lazard Capital Markets analyst Alexander Arrow cut his investment rating on Guidant to "sell" from "hold" on Monday, saying J&J may opt to renegotiate the acquisition price for Guidant. He estimated the cost for Guidant to replace all of the recalled devices at \$225 million.

However, several Wall Street analysts and investors on Monday said they did not expect the recall to derail the deal with J&J, noting device recalls are an inevitable part of the landscape in the medical technology industry.

"These are life-saving devices. They function well 99 percent of the time," said one portfolio manager who asked not to be named.

Eli Kammerman, an analyst with independent research firm Cathay Financial, estimated the financial impact of the recall to Guidant at "well under \$100 million," assuming that fewer than 30 percent of patients who have received the Guidant defibrillators request new devices.

"Guidant has more than sufficient cash on hand to fund those expenses," Kammerman said.

\*\*\*

51. During the Class Period, defendants knew and concealed:

(a) serious and alarming health issues encountered by patients caused by the malfunctioning and defective nature of the Company's defective devices;

(b) how the way in which the Company orchestrated its product design, manufacturing, quality, consumer complaint and corporate compliance functions prevented product failure investigations and other corrective actions from triggering responsible corporate actions, especially the timely recall of the Company's defective products;

(c) its failure to achieve affirmative corrective and preventative actions consistent with the spirit and letter of the Company's own corporate integrity guidelines, even after the Company had entered into a "corporate integrity agreement" with the Office of the Inspector General of the U.S. Department of Health and Human Services;

(d) the overwhelming threat to the deal defendants had forged with Johnson and Johnson for the sale of Guidant, including the threat to the ability of insiders to profit as a result of stock sales during the Class Period;

(e) the lack and insufficiency of communications to healthcare providers and patients regarding the defective nature of the Company's defibrillator products, even when adequate communications were essential to protect the lives of its implant patients; and

(f) the troubling decision to await overwhelming negative media accounts before taking affirmative actions regarding the Company's defibrillator products.

**DEFENDANTS' CLASS PERIOD STOCK SALES**

52. During the Class Period, defendants sold shares of their Guidant stock, in accordance with the following schedule:

<b>Defendant</b>	<b>Shares</b>	<b>Trade Date</b>	<b>Avg. Price</b>	<b>Total</b>
LORELL BEVERLY H	22667	05/23/05	\$74.00	\$1,677,358.00
LORELL BEVERLY H	23300	05/17/05	\$73.55	\$1,713,725.07
SPAULDING RONALD N	8200	05/10/05	\$73.27	\$600,785.01
SPAULDING RONALD N	50000	01/31/05	\$72.19	\$3,609,308.96
DOLLENS RONALD W	271404	04/07/05	\$74.38	\$20,187,311.77
NEELS GUIDO J	60000	02/08/05	\$73.02	\$4,381,279.03
BRAUER KEITH E	50000	01/31/05	\$72.30	\$3,615,055.99
MCCONNELL WILLIAM F JR	52000	01/31/05	\$72.26	\$3,757,420.01
	537571			\$39,542,243.84

**APPLICABILITY OF PRESUMPTION OF RELIANCE:**

**FRAUD-ON THE MARKET DOCTRINE**

53. At all relevant times, the market for Guidant's stock was an efficient market for the following reasons, among others:

(a) Guidant's stock met the requirements for listing, and was listed and actively traded on the New York Stock Exchange ("NYSE"), a highly efficient and automated market;

(b) As a regulated issuer, Guidant filed periodic public reports with the SEC and the NYSE;

(c) Guidant regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Guidant was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

(e) As a result of the foregoing, the market for Guidant's stock promptly digested current information regarding Interchange from all publicly available sources and reflected such information in Guidant's stock price. Under these circumstances, all purchasers of Guidant's common stock during the Class Period suffered similar injury through their purchase of Guidant's common stock at artificially inflated prices and a presumption of reliance applies.

#### **NO SAFE HARBOR**

54. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Guidant who knew that those statements were false when made.

## COUNT I

### **For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

55. Plaintiff incorporates ¶¶ 1-54 by reference.

56. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

57. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Guidant publicly traded securities during the Class Period.

58. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Guidant publicly traded securities. Plaintiff and the Class would not have purchased Guidant publicly traded securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

59. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Guidant publicly traded securities during the Class Period.

## COUNT II

### For Violation of §20(a) of the 1934 Act Against All Defendants

60. Plaintiff incorporates ¶¶1-59 by reference.

61. The Individual Defendants acted as controlling persons of Guidant within the meaning of §20(a) of the 1934 Act. By reason of their positions as officers and/or directors of Guidant, and their ownership of Guidant stock, the Individual Defendants had the power and authority to cause Guidant to engage in the wrongful conduct complained of herein. Guidant controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Guidant are liable pursuant to §20(a) of the 1934 Act.

### CLASS ACTION ALLEGATIONS

62. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Guidant publicly traded securities (the “Class”) on the open market during the Class Period. Excluded from the Class are defendants.

63. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Guidant had more than 325 million shares of stock outstanding, owned by hundreds if not thousands of persons.

64. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether the 1934 Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;

(c) Whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or deliberately disregarded that their statements were false and misleading;

(e) Whether the prices of Guidant's publicly traded securities were artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

65. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

66. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

67. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

**PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

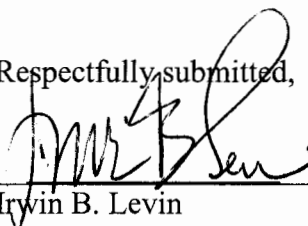
- A. Declaring this action to be a proper class action pursuant to FRCP 23;
- B. Awarding plaintiff and the members of the Class damages, interest and costs; and
- C. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: June 24, 2005

Respectfully submitted,



---

Irwin B. Levin  
Richard E. Shevitz  
COHEN & MALAD, LLP  
One Indiana Square, Ste. 1400  
Indianapolis, IN 46204  
Telephone: 317-636-6481  
Facsimile: 317-636-2593

*Local Counsel for Plaintiff*

SCOTT + SCOTT, LLC  
DAVID R. SCOTT  
NEIL ROTHSTEIN  
108 Norwich Avenue  
Colchester, CT 06415  
(860)537-5537  
Fax: (860)537-4432

-and -

ARTHUR L. SHINGLER III  
401 B Street, Suite 307  
San Diego, CA 92101  
Telephone: (619) 233-4565  
Facsimile: (619) 233-0508

*Counsel for Plaintiff*

**PLAINTIFF CERTIFICATION  
PURSUANT TO FEDERAL SECURITIES LAWS**

Mousca Yeroushalmi  
PSY Trading, Inc., ("Plaintiff"), declares, as to the claims asserted under the federal securities laws, that:

1. Plaintiff has reviewed the Complaint and retains Scott + Scott, LLC, and such co-counsel it deems appropriate to associate with, to pursue such action on a contingent fee basis.
2. Plaintiff did not purchase the security that is the subject of this action at the direction of Plaintiff's counsel, or in order to participate in any action.
3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.
4. Plaintiff's transaction(s) in the Guidant Corp ("GDT") security that is the subject of this action during the Class Period is/are as follows:

<u>No of Shares/Securities</u>	<u>Buy/Sell</u>	<u>Date</u>	<u>Price Per Share</u>
--------------------------------	-----------------	-------------	------------------------

5. During the three years prior to the date of this Certification, Plaintiff has not served, or sought to serve as a class representative in a federal securities fraud case, except as follows:

6. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this \_\_\_\_\_ day of \_\_\_\_\_, 2005, at \_\_\_\_\_ (city, state).

Printed Name: MOUSCA YERUSHALMI / PSY TRADING INC

Signature: \_\_\_\_\_

Mailing Address:  
(Please print)

Telephone #:

E-mail Address:

**REDACTED**

**SCHEDULE A – Guidant Corp**

<b>Date</b>	<b>Buy/Sell</b>	<b>Quantity</b>	<b>Price</b>
12/16/04	Buy	1000	\$72.10