

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

NEW YORK
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THE PEOPLE OF THE STATE OF NEW YORK, :
by ELIOT SPITZER, Attorney General of the :
State of New York, :

Plaintiff,

against -

GUIDANT CORPORATION,

Defendant. :

SUMMONS

Index No. 403656/05
Date of Filing:

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TO THE ABOVE-NAMED DEFENDANT:

You are hereby summoned and required to serve upon plaintiff's attorney an answer to the complaint in this action within thirty days after service is complete. In case of your failure to answer, judgment will be taken against you by default for the relief demanded in the complaint.

The basis of the venue designated is the county where the plaintiff has its business address, at Office of the Attorney General, 120 Broadway, New York, New York 10271-0332.

Dated: New York, New York
November 2, 2005

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State of New York
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By:

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK, :
by ELIOT SPITZER, Attorney General of the :
State of New York,

Plaintiff,

- against -

COMPLAINT
Index No.

GUIDANT CORPORATION,

Defendant. :

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TO: THE SUPREME COURT OF THE STATE OF NEW YORK

Plaintiff, the People of the State of New York, by their attorney, Eliot Spitzer,
Attorney General of the State of New York, alleges the following upon information and belief:

PRELIMINARY STATEMENT

1. Guidant Corporation (“Guidant”) manufactures and sells medical devices, including the implantable cardioverter defibrillator (“ICD”) known as the Ventak Prizm 2 DR Model 1861 (“Prizm 1861 defibrillator”), which is surgically implanted in the body of patients who are at high risk of sudden cardiac death due to abnormal heart rhythm. A properly functioning ICD detects life-threatening heart rhythm abnormalities and delivers an electric shock to the heart muscle, causing the heart to return to a normal rhythm. Without the electric shock therapy, the normal rhythm may not be restored, and the patient may die.

2. Guidant began selling the Prizm 1861 defibrillator in 2000. In February 2002, Guidant discovered a design flaw in the defibrillator that in some cases caused an electric short, diverting the electric energy into the device circuitry and resulting in the permanent loss of the defibrillator’s capacity to deliver the needed electrical shock to the heart.

3 In April and November 2002, Guidant made manufacturing changes to the Prizm 1861 defibrillator intended to remedy the systemic defect and prevent the short circuiting and resulting catastrophic failure of the device. Despite making these design changes, Guidant continued to sell Prizm 1861 defibrillators that had been manufactured before April 2002. Guidant did not disclose to physicians and patients that these devices contained a serious design flaw that had been corrected in later devices. In marketing and selling the Prizm 1861 defibrillator after the design changes had been made, Guidant did not even distinguish between defibrillators manufactured before and after April 2002, calling all of them the Ventak Prizm 2 DR Model 1861.

4. Guidant continued to conceal the design flaw in the Prizm 1861 defibrillators from physicians and patients until May 23, 2005, when Guidant became aware that on the following day The New York Times intended to expose the defect and that the company had continued to sell devices manufactured before the design change. Hours before the story appeared in The New York Times, Guidant issued a press release disclosing the defect and admitting that it had continued to sell defibrillators manufactured prior to April 2002. Guidant disclosed this information directly to physicians on June 17, 2005.

5. Thousands of Prizm 1861 defibrillators manufactured before April 2002 remain implanted in patients, and at least 28 have failed due to an electrical short related to the design flaw, including the device in at least one patient who died when his Prizm 1861 defibrillator failed.

6. By concealing and misrepresenting material – indeed critical – information concerning the Prizm 1861 defibrillators manufactured before April 2002, Guidant has engaged in repeated and persistent fraudulent conduct in violation of New York Executive Law § 63(12).

Accordingly, the Attorney General brings this action for permanent injunctive relief, to obtain restitution for patients in whom a Prizm 1861 defibrillator manufactured before April 2002 was implanted, for disgorgement of profits, and for all other proper relief.

JURISDICTION AND PARTIES

7. The Attorney General is authorized to seek a judgment which enjoins repeated or persistent fraudulent or illegal business acts or practices, including any misrepresentation, concealment or suppression of a material fact, and which awards damages and restitution for such acts. N.Y. Executive Law § 63(12).

8. Guidant Corporation is an Indiana Corporation. Guidant regularly conducts business within the State of New York and derives substantial revenues from goods sold in New York.

FACTUAL ALLEGATIONS

Background

9. The federal Food and Drug Administration (“FDA”) approves medical devices for use in humans. The agency categorizes medical devices as Class I, Class II or Class III devices, based on the degree of control that needs to be exercised over the devices to ensure they are safe and effective for their intended use. A device receives a Class III designation because it requires the greatest degree of control and either presents a potential unreasonable risk of injury or illness or purports to be for use in sustaining or supporting human life or as having substantial importance in preventing impairment of human health. 21 U.S.C. § 360c. The approval process differs depending on the class to which a device is assigned.

10. The FDA's approval of a medical device for marketing in the United States represents its finding that there is reasonable assurance of the safety and effectiveness of the device for its intended use and conditions of use. 21 C.F.R. § 860.7. The FDA also determines whether the medical device may only be dispensed by prescription and if there are any restrictions on the training of the practitioners who may dispense the device. The FDA has no authority to, and does not, make any determination that one approved brand or model of a medical device is superior to, or is safer or more effective than, another approved brand or model of the same type of device.

11. The FDA does not regulate the practice of medicine. Within New York, as in other states, the regulation of the practice of medicine is solely the responsibility of the State.

12. New York physicians, like other physicians, owe their patients fiduciary and professional obligations to exercise their independent professional judgment in making treatment recommendations and to recommend only those treatments that are appropriate for the individual patient. Patients rely on the professional judgment of their physicians in deciding whether to consent to a particular treatment and/or to purchase a particular medical device.

13. Patients who need to have an ICD implanted in their body routinely rely on the judgment and advice of their physicians, including the physician's recommendation as to which ICD is most appropriate for them. The physician's professional judgment is wholly outside the ambit of the FDA's oversight and control, as long as the FDA has approved the device that the physician selects.

14. In deciding which ICD to implant in a particular patient, physicians rely on a variety of sources of information, including information made available by the manufacturers of competing devices. Concealment of information material to the selection of an ICD for a

particular patient and misrepresentation of distinctly different devices as being identical or interchangeable deprives the physician of the ability to exercise independent professional judgment on behalf of the patient and to act in accordance with the professional and fiduciary obligations owed to the patient.

15. Concealing information, or providing misleading information, that is material to a decision regarding which ICD to purchase constitutes deceptive conduct that is directed at both the physician who prescribes a device and the patient who relies on that physician's professional judgment.

The Prizm 1861 Defibrillator

16. The Prizm 1861 defibrillator is a Class III device.

7. The FDA approved the Prizm 1861 defibrillator in 2000 to treat patients who have had or are at risk of developing life-threatening cardiac arrhythmias (abnormal heart rhythm). In August 2002, the indications for this device were expanded to include its use as a preventative treatment for patients who have had a prior heart attack and whose heart can no longer pump blood normally with each heartbeat. The FDA has not withdrawn its approval of the Prizm 1861 defibrillator, nor has it limited the conditions for which it is indicated.

Guidant Has Engaged in Repeated and Persistent Fraud in the Sale of Prizm 1861 Defibrillators.

18. In February 2002, Guidant discovered that deterioration in a wire insulator resulted in an electrical short in some Prizm 1861 defibrillators ("the design flaw"). According to Guidant, "[t]he short caused diversion of shock therapy energy away from the heart and into the device circuitry. Resultant circuit damage caused permanent loss of shock therapy and pacing." In other words, after the Prizm 1861 defibrillator short-circuited, it no longer worked. The device gave no warning or indication that it had experienced an electrical short and would no

longer function properly. Thus, a patient who relied on the device to detect and treat irregular heartbeat or other indicated condition would be at risk of sudden cardiac death, the very risk the Prizm 1861 defibrillator was supposed to prevent.

19. In April and November 2002, Guidant made manufacturing changes intended to prevent the short circuiting and resulting device failure in the Prizm 1861 defibrillator.

20. Guidant did not inform physicians of the possibility that Prizm 1861 defibrillators that they had implanted in their patients would fail due to an electrical short and that the company had made manufacturing changes to attempt to address this design flaw. Moreover, Guidant continued to sell defibrillators manufactured before the design change without disclosing either the flaw or the manufacturing changes made in 2002 to correct the flaw. Indeed, in its dealings with physicians, Guidant did not distinguish between the Prizm 1861 defibrillators manufactured before and after the design flaw was corrected. All of these devices, whether manufactured before or after the April and November 2002 manufacturing changes, were identified as Ventak Prizm 2 DR, Model 1861.

21. Approximately 13,900 Prizm 1861 defibrillators manufactured before the April 2002 manufacturing change remain implanted in patients in the United States, including patients in the State of New York.

22. Guidant has admitted that twenty-eight Prizm 1861 defibrillators have failed due to the design flaw, including one that failed in a patient who died when his Prizm 1861 defibrillator did not function properly due to an electrical short. Other patients whose Prizm 1861 defibrillator failed to deliver an electric shock to their heart while they suffered a dangerous abnormal heart rhythm did not die because the failure occurred while they were in the hospital or at a clinic where other rescue measures were available. According to Guidant, between 2002 and

the present, progressively more Prizm 1861 defibrillators failed each year. Guidant acknowledges that “the actual rate of failure may be greater than the reported rate. Death associated with device failure may be underreported, since ICDs are not routinely evaluated postmortem.”

23 On or about May 23, 2005, Guidant disclosed publically for the first time that the Prizm 1861 defibrillators manufactured before April 16, 2002 had a design flaw that made them prone to failure due to an electrical short and that the company had continued to sell the defective products even after it twice altered the manufacture of the device to attempt to eliminate this problem. Guidant’s disclosure occurred mere hours before these facts were disclosed in The New York Times and only after Guidant became aware that the newspaper intended to reveal this information on the following day.

24. On June 17, 2005, Guidant notified physicians of the design flaw and that the company would replace at no cost any Prizm 1861 defibrillator that was manufactured before April 16, 2002 which remained implanted in a patient where normal elective replacement indicators had not yet appeared. Guidant also informed doctors that it would pay up to \$2,500 of unreimbursed costs associated with surgically replacing the device. In New York City, and possibly elsewhere in New York State, the cost of replacing an ICD exceeds \$2,500 by a considerable amount.

25. Also on June 17, 2005, the FDA issued a nationwide notification that Guidant had recalled the Prizm 1861 defibrillators manufactured before April 16, 2002. The agency stated, “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.”

26. On July 1, 2005, FDA classified Guidant’s voluntary recall of the Prizm 1861 defibrillators manufactured on or before April 16, 2002 as a Class I recall. FDA explained that, “In a Class I recall, there is a reasonable probability that if a particular device is malfunctioning, the malfunctioning device will cause serious adverse health consequence or death.” The FDA did not require Guidant to “recall” the Prizm 1861 defibrillators, nor did it require Guidant to alter in any way the voluntary offer Guidant made for replacing the device or reimbursing patients for some costs associated with such replacement.

27. Between February 2002 and May 23, 2005, Guidant concealed from physicians and their patients who need an ICD implanted to treat life-threatening heart conditions information that was of critical importance in their decision about which ICD to select. Had they known of the design defect in the Prizm 1861 defibrillators manufactured before April 2002, some physicians would have recommended implanting other ICDs, as well as removing and replacing Prizm 1861 defibrillators manufactured before April 2002 that had already been implanted in their patients.

Guidant Has Engaged in Deceptive and Fraudulent Practices in the Sale of Other Medical Devices.

28. Guidant manufactures and sells medical devices in addition to the Prizm 1861 defibrillator, including other ICDs.

29. In June 2003, a wholly owned subsidiary of Guidant pled guilty in federal court to 10 felony counts. In the plea agreement, defendant’s wholly owned subsidiary admitted that during a 19-month period that ended in March 2001, it had failed to report to the FDA the thousands of serious injuries, including 12 deaths, that were caused by a medical device it

manufactured and sold for the repair of abdominal aortic aneurisms. In addition to pleading guilty, the company agreed to pay \$92.4 million to settle federal civil and criminal charges.

30. In August 2004, Guidant made manufacturing changes to two other implantable defibrillators it manufactures and sells, the Contak Renewal Model H135 and the Contak Renewal 2 Model H155 (“Renewal defibrillators”) to remedy a short-circuiting problem similar to the one in the Prizm 1861 defibrillator. As with the Prizm 1861 defibrillator, the electrical short in the Renewal defibrillators would cause the device to fail without warning. The Renewal defibrillators are also indicated for the treatment of life-threatening arrhythmias. Guidant did not inform physicians or patients of the defect in the Renewal defibrillators until May 2005, unnecessarily depriving physicians and patients of the information they needed to make treatment and purchasing decisions concerning implantable defibrillators during a nine-month period.

CAUSE OF ACTION
REPEATED AND PERSISTENT FRAUD

31. Executive Law § 63(12) authorizes the Attorney General to bring an action to enjoin and obtain restitution and damages for “repeated fraudulent . . . acts or . . . persistent fraud . . . in the carrying on, conducting or transaction of business,” including “any deception, misrepresentation, concealment [or] suppression” of a material fact.

32. By engaging in the acts and practices described above, Guidant has engaged in and continues to engage in repeated fraudulent acts or persistent fraud in violation of Executive Law § 63(12).

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the People of the State of New York, respectfully requests that a judgment and order be entered that:

A. Permanently enjoins Guidant from engaging in the deceptive, fraudulent and unlawful practices alleged herein;

B. Enjoins Guidant from failing to make available at no cost on a publicly accessible Web site in non-technical language all information concerning Class II and Class III medical devices it manufactures or sells that is material to a physician's independent professional judgment about which brand or model of a type of device to recommend to a patient in need of the device or that is material to a patient's judgment about whether to consent to and purchase such treatment;

C. Directs Guidant to pay restitution and damages to all aggrieved consumers and/or third-party payers, including government health programs, which restitution and damages shall include, but not be limited to, the total cost of explanting a Prizm 1861 defibrillator manufactured before April 16, 2002 and replacing it with the ICD of the patient's choice, whether or not it is manufactured by Guidant, and disgorgement of all profits Guidant derived from the sale of Prizm 1861 defibrillators manufactured before April 16, 2002 and sold after February 2002;

D. Awards Plaintiff costs, including additional costs in the amount of \$2,000 pursuant to C.P.L.R. § 8303(a)(6); and

E. Grants all other relief that is just and proper.

Dated: New York, New York
November 2, 2005

Respectfully submitted,

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Attorney for Plaintiff
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