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Citing Flaws, Maker Recalls Heart Devices

By Barry Meier

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The Guidant Corporation said yesterday that it was recalling about 29,000 implanted heart devices because of flaws that might cause them to short-circuit when they are supposed to deliver a potentially life-saving shock.

The recall, which comes at the urging of the Food and Drug Administration, involves three models of defibrillators made by Guidant. In the case of one model, the Ventak Prizm 2 DR Model 1861, Guidant did not tell doctors for more than three years that it was prone to electrical failure because of a design flaw. The company also disclosed yesterday for the first time that two other Guidant units had also repeatedly short-circuited.

The company said it was aware of two recent deaths involving the units at issue. It is not clear how much the recalls may cost Guidant.

While the action is technically a recall, it will be up to patients and their doctors to decide whether to undergo surgery to replace the affected devices. Such decisions are typically based on the age and health of a patient and the physician's assessment of a device's risk.

The recall comes as F.D.A. officials continue their review of Guidant's handling of issues surrounding the products, particularly the Prizm 2 DR. The other models are the Contak Renewal and Contak Renewal 2, which are more complex defibrillators intended for patients with severe heart failure.

The F.D.A. urged affected patients to contact their doctors but did not take a position on whether the devices should be replaced.

Defibrillators are surgically implanted in the chest under the skin. If the heart is beating chaotically, the defibrillator emits an electrical jolt in an effort to restore it to normal rhythm.

In a statement yesterday, Ronald W. Dollens, chief executive of Guidant, said the company was taking the actions because it wanted to share information about problems "in a small subset of Guidant devices."

Guidant said it would provide free replacements for the devices, which can cost up to $25,000. "We will work with physicians as they decide how best to treat their patients," Mr. Dollens added.

But yesterday's disclosure that Guidant also knew that other popular company models beside the Prizm 2 were prone to short-circuiting raises further questions about how the company handled such issues.

An F.D.A. official also questioned whether Guidant had acted properly when it recently rushed out a letter to doctors notifying them that the Prizm 2 had short-circuited in over 25 known cases, including the March death of a 21-year-old student.

The company took the action late last month when it became aware that problems with the device, which date back to 2002, were going to be publicized in other forums.

Tim Ulatowski, the director of the agency's Center for Devices and Radiological Health, said Guidant should have treated the matter as a recall at that time.

Johnson & Johnson, which announced a plan in December to acquire Guidant for $25.4 billion largely to gain its cardiac device unit, issued a statement yesterday saying that while it continued to work to complete the deal, it was concerned about the developments. Last year, Guidant had $3.8 billion in sales, about half from implantable defibrillators.

"The events reported by Guidant are serious matters, and Johnson & Johnson is engaged in discussions with Guidant to help the company understand the issues," the statement read.

In trading on the New York Stock Exchange, shares of Guidant fell 84 cents a share to close at $72.46 a share.

Guidant has said it does not recommend that doctors replace the Prizm 2 model because it is reliable and because the additional surgery poses extra risks.

In April 2002, the company changed the way it manufactured the device to eliminate the electrical flaw. It has said it has not received similar complaints about devices made after that date. About 17,000 devices made before April 2002 are still implanted in patients, 13,900 of them in this country.

In the case of the Contak Renewal and Renewal 2 models, Guidant also urged that physicians closely follow how well the device is functioning, but did not make a recommendation one way or the other regarding replacement. Along with a defibrillator, the units have pacemaker functions that regulate beating for both sides of the heart.

The company said that internal testing showed that the failure rate of Renewal products might increase over time from a current rate of 0.09 percent to a range of 0.2 percent to 0.6 percent. About 11,900 Renewal products are still implanted in patients worldwide, about 6,700 of them in this country.

In February, another defibrillator maker, Medtronic, notified doctors that the battery used in one of its models was draining far faster than expected. It said the problem could become worse over time and affect 0.2 percent to 1.5 percent of its units. About 13,000, or 15 percent, of the 87,000 patients implanted with the device have had it replaced.

In many respects, the issues and Guidant's actions in the cases of the Prizm 2 and Renewal models parallel each other.

After the March death of a college student, Joshua Oukrop, doctors in Minnesota learned from Guidant that the Prizm 2 defibrillator they had implanted in him in 2001 had a history of electrical failures related to a design flaw.

The physicians, who had been treating Mr. Oukrop for a genetic heart disease that put him at risk of sudden cardiac arrest, said they urged Guidant at that time to notify other doctors. But company officials said they did not plan to do so because they did not see the problem as significant. The company did send a letter to doctors about the device in late May just as The New York Times was publishing an article about the Prizm 2.

In the aftermath, the F.D.A. began reviewing Guidant's handling of the matter. It was during that process that agency officials began to look at the Renewal devices, said Mr. Ulatowski, the F.D.A. official.

"We always inquire whether a problem caused by a design problem in one product might exist in other products," he said.

Mr. Ulatowski added that Guidant, through a filing, had notified the F.D.A. about manufacturing changes it made last August to correct a short-circuiting problem in the Renewal models.

However, only during recent reviews did the agency become aware of the scope of the problem. While Guidant previously received 14 reports of electrical failures in Renewal devices produced before August, it received a report on May 30 of the death of a patient who had been implanted with a unit that failed in a similar way.

It also appears that Guidant may have continued to sell older Renewal models in its inventory after improved versions were available, as it had done with the Prizm 2 defibrillator. Yesterday, Guidant officials declined to comment about the issue.

Since the controversy over the Prizm 2 began, Guidant has insisted that it made all required reports to the F.D.A. about device problems.

But under agency guidelines, the company was also required to undertake an internal assessment of the patient risks posed by the device's electrical problems once it discovered them.

Such an analysis must include an evaluation of how frequently the flaw is likely to occur, its danger and whether doctors and patients would become aware of it as a result of mechanisms in the device, like a beep that indicates the battery is dying.

Mr. Ulatowski, the F.D.A. official, said the agency was still reviewing Guidant records. "We are taking a very careful look at the events that occurred and what decisions were made or were not made," he said.

Guidant has acknowledged that because the flaws involved a short-circuiting of a device while it was charging to deliver a high-voltage shock, it could occur unpredictably.

A group that represents doctors treating heart patients, the Heart Rhythm Society, is expected to soon set up a task force to press for standards governing device makers' notifications of doctors about problems with implanted heart units. In his statement yesterday, Mr. Dollens, the Guidant chief executive, said he supported that effort.

In addition to the Prizm 2 and the two Renewal models, Guidant said yesterday that it was recalling 21,000 other defibrillators that had a programming error that might affect device performance. The company said patients could have the device reprogrammed during their next regular doctor's visit.

Guidant said the affected units were the Prizm AVT, Vitality AVT, Renewal 3 AVT and Renewal 4 AVT.