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.