A division of one of the country's largest makers of medical devices pleaded guilty yesterday to 10 felonies, admitting that it lied to the government and hid thousands of serious health problems, including 12 deaths, caused by one of its products.

The sweeping case against the division of the device maker, the Guidant Corporation, resulted in $92.4 million in criminal and civil penalties, the largest ever imposed against a maker of medical devices for failing to report problems to the government.

The problems with the device, which was used to treat a weakened blood vessel in the abdomen without surgery, centered on the system used to insert it. The equipment could become lodged, potentially requiring emergency surgery to remove it. In some cases, it was broken into pieces before being removed -- a technique devised by sales representatives. Guidant hid results that its product failed to work properly about one of every three times it was used.

As part of the plea, the Guidant division, Endovascular Technologies, also agreed to cooperate in investigations against executives who might have been involved in wrongdoing. As part of that agreement, the company waived attorney-client privilege, meaning that statements made by any employees to company lawyers during the investigation will now be available as potential evidence.

But the company's legal troubles are far from over. It already faces a number of lawsuits from individuals, and thousands of patients whose procedures did not go as expected could still bring cases. It must also complete aspects of a civil settlement with the Department of Health and Human Services, which would allow it to avoid exclusion from government programs like Medicare.

Guidant, which had $612 million in net income last year, may be little known among the public, but it has been at the leading edge of one of the most important disciplines of medicine to emerge over the last 25 years. That field, known as interventional cardiology, uses tiny devices called stents to remove the obstructions in coronary vessels that can lead to chest pain.

In 1999, Guidant brought out a new type of graft intended to strengthen the aorta, the main vessel that comes from the heart, as it passes through the abdomen. A weakening of that vessel, known as an abdominal aortic aneurysm, is a potentially life-threatening condition that frequently occurs in people with heart disease. Soon after the introduction of the product, the Ancure Endograft System, the company was aware of significant flaws in the system used to insert the device but decided not to notify the Food and Drug Administration of the scope of the problem, as required under federal law, according to the charges, which were filed in Federal District Court in San Francisco.

Guidant pulled the Ancure device from the market in March 2001, made changes and reintroduced it five months later. The company said in a statement yesterday that because the initial risk from the device came from the equipment used to insert it, patients who have the device are not in danger. Guidant, based in Indianapolis, said that the device continued to demonstrate positive long-term results for patients.

The charges against Endovascular Technologies, a wholly owned subsidiary that Guidant acquired in 1997, describe a company that allowed marketers to influence its scientific decisions when faced with a public health risk. Indeed, the charges say, sales representatives devised a method of their own to deal with problems, telling doctors to physically break into pieces the system used for inserting the graft while it was in a patient's vessel.

Guidant has still more steps to take before the government's civil case is resolved. As part of the agreement with Health and Human Services, both Guidant and its subsidiary are required to put in place corporate integrity agreements. In exchange for adopting those requirements -- the details of them are still subject to approval by the government -- Health and Human Services has agreed not to seek to bar the companies from any government programs, including Medicare.

Shares of Guidant fell $2.67, or 6.2 percent, to $40.56.

Law enforcement officials hailed the plea, which they said exposed failures that had placed patients at serious risk.

"Because of the company's conduct, thousands of patients underwent surgeries without knowing the risks they faced, and their doctors -- through no fault of their own -- were unprepared to deal with those risks," said Kevin V. Ryan, the United States attorney in San Francisco. "These actions were criminal, and I am happy to say that today, for the first time in more than three years, the public will be able to learn the truth."

Medical specialists expressed both surprise and concern about the criminal charges. "Whenever a company has a serious ethical, and in this case legal, lapse, it always raises concerns across the product line," said Dr. Steven Nissen, a cardiologist at the Cleveland Clinic.

Still, Dr. Nissen, who has worked with a Guidant project in the past, expressed surprise at the plea, saying that the company had always struck him as ethical.

But Nancy Hersh, a lawyer who represents seven patients who were injured and the families of two who died after the procedure to insert the device, described the criminal plea as an important step forward. "It's absolutely fantastic, not just for my clients, but for the F.D.A. and for the safety of the public," Ms. Hersh said.

Historically, doctors dealt with abdominal aneurysms through complex surgery. That entailed opening the abdominal cavity, moving aside the patient's internal organs, finding the aorta and locating the aneurysm -- a spot where the vessel is weakened and balloons out. Once that is found, the surgeon would attach a graft to strengthen that point in the aorta. If left untreated, the aorta could burst and cause death.
The newer method advanced by Guidant avoided the dangers and complications of surgery. With it, a doctor inserted a catheter containing a polyester graft into an artery in the groin, then threaded it through the body until it reached the aneurysm.

The F.D.A. approved Guidant's device on Sept. 30, 1999 -- the day a rival product also received approval. But even before the approval date, the charges say, company employees knew that doctors were finding the delivery system difficult to use.

Soon after sales began in the United States, the charges say, doctors and others began to report to the company malfunctions with the delivery system, resulting in its becoming lodged in the body of the patient. As a result, doctors were forced to perform surgery -- opening up the abdominal cavity -- simply to remove the delivery system.

Faced with these difficulties, the charges say, sales representatives, who were often present when the procedure was performed, began telling doctors to break off the handle of the delivery system if it became stuck and extract it in pieces. The charges say that solution was devised in part by the sales representatives themselves, with no testing to prove it safe or effective.

In one procedure, conducted in January 2000, the handle-breaking technique was performed unsuccessfully and the patient died. Though employees insisted that this meant the procedure had to be tested, Endovascular Technologies failed to do so and continued to recommend that doctors break the handle.

Each significant problem was required to be reported to the F.D.A., but the company failed to do so. Indeed, in July 2000, an F.D.A. inspector asked for records of all instances in which the delivery system experienced problems. The company turned in a list of 55 complaints. Throughout the life of the device, it submitted 172 reports of problems.

But, the complaint said, the real number was much higher: 2,628 additional reports of problems, out of a total of 7,632 devices that were sold.

The full scope of the problem finally came to the attention of the F.D.A. in the fall of 2000, when seven anonymous employees sent a letter providing details about the failures and problems that were occurring. On March 16, 2001, Guidant removed the device from the market.

Seven days later, the company disclosed to the F.D.A. that thousands of patients had experienced serious problems from the delivery system.

The company made changes and put the device back on the market in August 2001.