FDA News Release

OtisMed Corporation former CEO sentenced for shipping adulterated knee replacement cutting guides

Corporation had previously paid more than $80 million to resolve criminal and civil investigations

For Immediate Release

June 26, 2015

Release

Today, the U.S. District Court of the District of New Jersey sentenced the OtisMed Corporation's (OtisMed) former chief executive officer, Charlie Chi, to 24 months in prison and also ordered him to serve one year of supervised release and to pay a $75,000 fine.

In December 2014, OtisMed agreed to pay more than $80 million to resolve related criminal and civil liability related to charges of distributing adulterated medical devices with intent to defraud and mislead. At that same time, Chi pleaded guilty to introducing adulterated medical devices into interstate commerce.

The sentencing was the culmination of a long-term investigation conducted jointly by special agents from the FDA's Office of Criminal Investigation and from the Department of Health and Human Services' Office of the Inspector General.

"With more than 600,000 knee replacements performed each year, patients rely on FDA to help ensure that the devices are safe and work as intended. When manufacturers ignore FDA requirements, they risk endangering patients' health and quality of life," said George M. Karavetsos, director of the FDA's Office of Criminal Investigations. "We will continue to protect the public health by bringing to justice those who disregard FDA regulations."

The OtisKnee was used by surgeons during total knee arthroplasty (TKA), commonly known as knee replacement surgery. OtisMed marketed the OtisKnee cutting guide as a tool to assist surgeons in making accurate bone cuts specific to individual patients' anatomy based on magnetic resonance imaging (MRI) performed prior to surgery. None of OtisMed's claims regarding the OtisKnee device were evaluated by the FDA before the company made them in advertisements and promotional material.

Between May 2006 and September 2009, OtisMed sold more than 18,000 OtisKnee devices, generating revenue of approximately $27.1 million.

On Oct. 2, 2008, OtisMed submitted a pre-market notification to the FDA seeking clearance to market the OtisKnee. The company had not previously sought the FDA's clearance or approval, and had been falsely representing to physicians and other potential purchasers that the product was exempt from such pre-market requirements.

On Sept. 2, 2009, the FDA sent OtisMed a notice that its submission had been denied, noting that the company had failed to demonstrate the OtisKnee was as safe and effective as other legally marketed devices. One week after the FDA denied OtisMed's request for clearance, the company shipped approximately 218 OtisKnee guides from California to surgeons throughout the U.S.

"Today's sentencing of OtisMed's CEO ought to send a clear message to others in positions of authority within the medical device and pharmaceutical industries: the Department of Justice will vigorously prosecute not only corporations, but also the individuals at their helm who are responsible for endangering public health and safety in pursuit of profit," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division.

"The defendant betrayed the trust of patients whose doctors were using his unapproved surgical device for a serious medical procedure," said U.S. Attorney for the District of New Jersey Paul J. Fishman. "With everything else people have to deal with when they are facing surgery, they shouldn't have to worry whether their doctor is using equipment that has been approved for use. The punishment meted out to Chi and his company is appropriate."

The case was prosecuted by Chief Jacob T. Elberg of the U.S. Attorney's Office of the District of New Jersey Health Care and Government Fraud Unit and Trial Attorney Ross S. Goldstein of the Department of Justice's Civil Division's Consumer Protection Branch.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###