US demands data on older medical devices

Reuters

WASHINGTON, DC, USA: US regulators have ordered makers of 25 types of medical devices to supply safety and effectiveness data so the US government can decide whether the products must undergo the most stringent review process. The order addresses complaints that the Food and Drug Administration had allowed some devices that were sold before 1976 without agency approval to remain on sale without a thorough evaluation.

The devices include metal hip joints, dental implants and screws used for spinal surgery, an FDA notice said. The FDA oversees medical devices ranging from simple bandages and tongue depressors to the most complex products such as pacemakers and heart-valve replacements. Each is classified based on the level of risk to patients. The most dangerous are labeled “Class III” and subject to the most rigorous level of review.

Some Class III devices that were on the market before 1976 were allowed to go through a less stringent evaluation while the FDA developed regulations to address them or decided they were less risky.

In January, the Government Accountability Office criticized the FDA for failing to complete work on all of the pre-1976 Class III devices more than three decades later.

The GAO, a watchdog arm of Congress, urged the FDA to “expeditiously” deal with the remaining products. The order is the first step toward completing that process, FDA officials said.

“We are now committed to addressing this quickly,” Kate Cook, associate director of regulation and policy in the FDA’s device center, said in an interview.

Nobel Biocare wins patent ruling in Germany

Reuters

ZURICH, Switzerland: Swiss dental implant maker Nobel Biocare said it had won a German court ruling in a patent infringement case brought by Materialise Dental in relation to Nobel Biocare’s NobelGuide software.

“Nobel Biocare said it had obtained a positive decision from the German Federal Patent Court invalidating all relevant claims of Materialise’s patent, which according to Materialise, is infringed by Nobel Biocare’s NobelGuide software,” Nobel Biocare said in a statement.

Nobel Biocare expects the Higher Regional Court Dusseldorf to rule favourably on its appeal against the first decision of the Lower Regional Court Dusseldorf in August 2007, which found Nobel Biocare had infringed Materialise’s patent.

Last month, Nobel Biocare won a ruling in a US litigation with Materialise.

Dental biomaterials market growth to continue despite challenging 2009, report says

Although dental biomaterials are being used in a growing proportion of dental implant procedures, the market for these products will be dampened by the global financial crisis in the coming years as many patients postpone dental implant procedures or choose less expensive alternatives such as crowns.

This is the conclusion of the US Markets for Dental Biomaterials 2009 report from Millennium Research Group, a global authority on medical technology market intelligence and leading provider of strategic information to the health care sector.

The US market for dental biomaterials continued to grow in 2008 due to several significant market events: Biomet 3i’s Enduron and Novabone’s Nova-Ker were launched in the US in the second quarter of 2008; the US import ban on Straumann’s Endogain and Bone, Ceramic we lifted in August, making these products available toward the end of the year; Curasan’s dental business was purchased by Riemsler Arness, a German pharmaceutical company; Regeneration Technologies and Togos Medical merged and now operate under the new name RTI Biologics; and LifeCore Biomedical’s dental division merged with Keystone Dental following LifeCore Biomedical’s acquisition by Wachburg Finance.

“Although dental biomaterials continued to grow in 2008 due to several significant market events, the US market for dental biomaterials will continue to face a challenging environment in 2009,” said Chad Gervais, senior research analyst at Millennium Research Group. “Marketers will have to focus on cost-conscious consumers, so delivering new products and technologies that address unmet needs will be critical for growth in the dental biomaterials market.”

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