FDA Clearance For A Second Generation Interbody Fusion Device System Granted

/PRNewswire/ -- Amedica Corporation, aspinal and reconstructive medical device manufacturer, announced today it has received 510(k) clearance from the U.S. Food and Drug Administration to legally market a second generation family of cervical and lumbar interbody fusion devices (IBF) manufactured with the company's proprietary Silicon Nitride biomaterial. The product portfolio expansion offers design enhancements including a threaded insertion feature, additional footprints, and design elements that will allow surgeons to perform minimally invasive and lumbar lateral interbody fusion (LLIF) approaches.

The most common reason for performing a spinal fusion is to eliminate the pain caused by abnormal motion of the vertebrae as a result of diseased discs, slippage of the vertebrae, or other degenerative spinal conditions, and the goal of the procedure is to immobilize the faulty vertebrae themselves. An interbody fusion device is a prosthesis used in spinal fusion procedures to restore and maintain disc space height following a spinal decompression while fusion occurs. These devices are often filled with bone or other materials in order to promote a spinal fusion at the level that the disc was removed.

The development of a second generation of interbody implants made from Silicon Nitride positions Amedica as a strong competitor in the $1.5 billion IBF market and now allows the company to enter the $147 million LLIF segment. Minimally invasive LLIF procedures may offer improved patient outcomes by allowing reduced operative time, post-operative pain and hospital stays, as well as a rapid return to normal activity. Among the challenges in performing an LLIF procedure is the proximity to nerves during implantation requiring the use of neuromonitoring to ensure precise, safe placement of the implant. Silicon Nitride is semi-radiolucent which enables an exact view of the implant for precise intraoperative positioning, thereby alleviating this challenge.

"Amedica is now better positioned to deliver a technology that can change the standard of care for spinal surgery," said Eric K. Olson, President and Chief Executive Officer, Amedica. "The enhancements we have made to our interbody line of products including the LLIF devices speak to our long term commitment to improve interbody fusion procedures by providing a premium product that enhances the surgeon experience while dramatically improving patient outcomes."

Earlier this month, Amedica announced the expansion of biomaterial claims for its Silicon Nitride Interbody Fusion Devices. Data published in two peer-reviewed studies demonstrate that Silicon Nitride provides superior osteointegration and anti-infective capabilities when compared to products comprised of poly-ether-ether-ketone (PEEK) or titanium (Ti). The first products of this family are slated to launch

in the fourth quarter of 2012.

Additional information about the company's complete line of products may be found at www.amedica.com.

Source URL (retrieved on *07/24/2014 - 12:56am*):
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