

Amedica Submits 510(k) Application to FDA for Composite Spinal Interbody Spacers With Porous Silicon Nitride Center

SALT LAKE CITY, Feb. 12, 2015 (GLOBE NEWSWIRE) -- Amedica Corporation (Nasdaq:AMDA), a company that develops and commercializes silicon nitride ceramics as a biomaterial platform, announced today that it has filed a submission for 510(k) clearance of the Valeo C Interbody with CsC Osteo-Conductive Scaffolding ("Valeo C^{CsC}") with the U.S. Food and Drug Administration ("FDA") relating to its composite silicon nitride spinal interbody devices.

"Following the impressive cervical fusion outcomes from our CASCADE clinical trial, I am proud to announce that a 510(k) application for our Valeo C^{CsC} silicon nitride devices has been submitted to the FDA, and has passed their administrative review," said Dr. Sonny Bal, chairman and CEO of Amedica Corporation. "The product is already cleared for sale in Europe. With the FDA application, we now seek to achieve clearance in the U.S. for our novel, porous synthetic interbody device that has shown fusion rates equivalent to a patient's own bone. The timer has now started with the FDA and we look forward to having the 510(k) reviewed and cleared. We continue to keep our potential and existing customers in close contact and maintain preparedness to begin domestic shipments as soon as clearance is received."

Pursuant to Section 510(k), the FDA has 90 days in which to clear the Class II medical device for commercial distribution or to seek additional information. The FDA previously confirmed that it would review the product as a medical device. Following notification of FDA clearance, the Company would immediately have the right to commence manufacturing, marketing and sales of the product in the United States and its possessions subject to FDA jurisdiction.

About Amedica Corporation

Amedica is focused on the development and application of medical-grade silicon nitride ceramics. Amedica markets spinal fusion products and is developing a new generation of wear- and corrosion-resistant implant components for hip and knee arthroplasty. The Company manufactures its products in its ISO 13485 certified manufacturing facility and, through its partnership with Kyocera, the world's largest ceramic manufacturer. Amedica's spine products are FDA-cleared, CE-marked, and are currently marketed in the U.S. and select markets in Europe and South America through its distributor network and its growing OEM partnerships.

For more information on Amedica or its silicon nitride material platform, please visit www.amedica.com.

Forward-Looking Statements

This press release contains statements that constitute forward-looking statements within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended by the Private Securities Litigation Reform Act of 1995. Forward-looking statements contained in this press release include the intent, belief or current expectations of Amedica and members of its management team with respect to Amedica's future business operations as well as the assumptions upon which such statements are based. Forward-looking statements include specifically, but are not limited to our expectations that the FDA will review and clear the 510(k) and that we will be prepared to begin domestic shipments if and as soon as clearance is received. Such statements are subject to risks and uncertainties such as the timing and the results of FDA review of our 510(k) and success of new product introductions, physician acceptance, endorsement, and use of Amedica's products. Additional factors that could cause actual results to differ materially from those contemplated within this press release can also be found in Amedica's Risk Factors disclosure in its Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 31, 2014, and in Amedica's other filings with the SEC. Amedica disclaims any obligation to update any forward-looking statements.

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