News Release

# Medical Device Using Evonik's VESTAKEEP® PEEK Receives First FDA Spinal 510(K) Approval

## K7C™ Cervical Spacer Gains Intervertebral Body Fusion Clearance

PARSIPPANY, N.J., February 5, 2013 – K7 LLC's K7C™ Cervical Spacer, a spinal implant device using Evonik's VESTAKEEP® PEEK (polyetheretherketone), has received the U.S. Food and Drug Administration's (FDA) 510(k) approval for use as an Intervertebral Body Fusion (IBF) device.

This marks the first time a VESTAKEEP® PEEK-based spinal fusion medical device has gained 510(k) approval from the FDA. The K7C™ Cervical Spacer is one of several PEEK-based spinal implant devices being developed by K7 LLC.

Michael Smith, founder and CEO of K7 LLC attributed VESTAKEEP® PEEK's durability as a key component in gaining FDA 510(k) clearance. "We could not be more pleased with the test results and material durability of VESTAKEEP® PEEK", said Smith. "The inherent strength and added ductility have created new possibilities for our PEEK implant designs."

Evonik's customers can reference the VESTAKEEP® PEEK product line Masterfiles (MAF), documents containing comprehensive test data on the product's mechanical and biocompatible properties that meet FDA regulatory requirements, to help guide future registration processes for implant medical devices.

"Creating innovative solutions for our customers is a core component of Evonik," said Sanjeev Taneja, vice president of Evonik's High Temperature Polymers Business. "The FDA approval is a testament to the product quality of VESTAKEEP® PEEK and the strength of its MAF. It is also an example of the long-term commitment Evonik has in the medical device and orthopedic industries. This approval validates Evonik as a true player in the implant PEEK market."

VESTAKEEP® PEEK is known for its superior biocompatibility and biostability. Its excellent sterilization resistance and good combination of stiffness and ductility make it suitable for medical implant applications that must meet extremely high mechanical, thermal, and chemical requirements.

“Significant investments and thorough material testing have been completed on the VESTAKEEP® PEEK product line to ensure Masterfile strength and preparedness,” said Kenneth Ross, Evonik’s VESTAKEEP® medical business development manager in North & South America. “We know VESTAKEEP® PEEK will serve as an outstanding medical material driving innovation in new product ideas and metal replacement developments.”

The VESTAKEEP® PEEK iGrade material also has regulatory clearance for spinal implants in Europe and Asia. With this 510(K) approval, customers will now have easier access to regulatory approvals in the United States market.

Evonik’s VESTAKEEP® PEEK products will be exhibited at the Medical Design and Manufacturing (MD&M) West show in Anaheim, Calif., on February 12-14, and the American Academy of Orthopedic Surgeons (AAOS) show in Chicago, Ill., on March 20-22.

For more information about VESTAKEEP® PEEK product lines, please visit: www.evonik.com/vestakeep.

For additional information about Evonik in North America, please visit website: www.evonik.com/north-america.

**Company information**

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. Its activities focus on the key megatrends health, nutrition, resource efficiency and globalization. Profitable growth and a sustained increase in the value of the company form the heart of Evonik’s corporate strategy. Evonik benefits specifically from its innovative prowess and integrated technology platforms.

Evonik is active in over 100 countries around the world. In fiscal 2011 more than 33,000 employees generated sales of around €14.5 billion and an operating profit (adjusted EBITDA) of about €2.8 billion.



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