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

The Associated Press

PARSIPPANY, N.J. - 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 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,” says 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,” says Sanjeev Taneja, vice president of Evonik’s High Temperature Polymers Business. “The FDA approval is a testament to the product quality 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.”

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

“Significant investments and thorough material testing have been completed on the product line to ensure Masterfile strength and preparedness,” says Kenneth Ross, Evonik’s VESTAKEEP medical business development manager in North & South America. “We know it 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, visit: www.evonik.com/vestakeep [1].

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Links:
[1] http://www.evonik.com/vestakeep