

# Solvay's Zeniva PEEK Passes Biocompatibility Testing in China

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Solvay Specialty Polymers, a leading global supplier of high-performance polymers, announced today that Zeniva polyetheretherketone, one of the four products comprising its family of Solviva Biomaterials offered for use in implantable devices, has successfully passed the biocompatibility testing at the China Food and Drug Administration's Tianjin Medical Device Quality Supervision and Inspection Center.

'Obtaining this important biocompatibility testing report facilitates the strategic implementation and launching of Solviva Biomaterials in the China market place,' said Kendra Shoulders, Director of Global Regulatory Affairs for Healthcare, Solvay Specialty Polymers. 'This essential recognition will help local medical OEMs to gain regulatory approval from the China Food and Drug Administration for their implantable devices.'

The inspection center at Tianjin is recognized as the most influential testing agency in the field of orthopedics in China. The test took over a year to complete and during this lengthy process, properties of Zeniva PEEK such as sensitization, intracutaneous toxicity, acute systemic toxicity, sub-chronic toxicity, genotoxicity and bone implant compatibility tests were rigorously examined to ensure biological safety in the human body, an absolute priority for implantable medical devices.

'Solvay's experience as a key materials supplier to the healthcare industry spans more than 25 years. With our broad product portfolio we are firmly positioned as a strategic supplier to the Chinese healthcare industry,' added Dr. Luke Du, Managing Director Asia, and Executive Vice President Solvay Specialty Polymers. 'Obtaining this local and important biocompatibility testing report for Zeniva PEEK signals our further commitment to both national and multi-national medical OEMs.'

Zeniva PEEK boasts a modulus very close to that of cortical bone plus excellent fatigue resistance and toughness. It is offered for use in implantable medical devices for spine, orthopedics, cardiovascular and dental applications. In addition, ZenivaPEEK offers numerous advantages over metals, such as reduction of stress shielding, no heavy metal allergy or ion erosion, and has radiolucent properties which allow x-ray and CT scanning procedures without interference.

Solvay's family of Solviva Biomaterials has been commercially available in China since 2013. In addition to Zeniva PEEK, the product line features Veriva polyphenylsulfone (PPSU), which combines unsurpassed toughness with transparency and excellent biocompatibility and Eviva polysulfone (PSU), a transparent, biocompatible polymer that offers high strength and toughness.

Solviva Biomaterials can be sterilized using all conventional methods including gamma radiation, ethylene oxide, and steam. These sterilizable products are available in grades for injection molding or extrusion, as well as stock shapes for machined components.

The entire range of thermoplastic Solviva Biomaterials is manufactured in an ISO 13485 registered facility and under the relevant aspects of current Good Manufacturing Practices. Solvay's biomaterial manufacturing processes are carefully validated, and enhanced controls provide product traceability. In addition, all materials are tested in an ISO 17025 accredited lab.

Source ENP Newswire