FDA Reclassification Paves Regulatory Pathway for Invibio PEEK-OPTIMA™ Spinal Rods

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Request for Reclassification

Until recently, posterior spinal rods and rigid pedicle screw systems, fell under the FDA Order 522 for Class III devices. Class III devices are considered "highest risk" and must follow the FDA's most stringent regulatory pathway, which requires a vigorous Premarket Application (PMA). Class III devices require a robust and completely independent clinical history not based on predicate devices, and therefore can lengthen the time and cost to market.

Invibio Biomaterial Solutions, along with other medical device manufacturers, were requested to submit to the order to reclassify spinal rods and rigid pedicle screw systems, supporting a modification to allow semi-rigid spinal rods to remain Class II devices.

Clinical and biomechanical evidence from over 51,000 PEEK Rod implantations was submitted in support of reclassifying PEEK-OPTIMA Spinal Rods as a Class II device. Class II devices, like Class III devices, require general and special controls that ensure compliance with the FDA's best quality and manufacturing processes, proper labeling and reporting, and adherence to other FDA-imposed special controls that ensure device safety and effectiveness. However, in lieu of the very involved PMA process, Class II devices typically follow the Premarket Notification 510(k) pathway, which provides a much clearer and timely route to market.

Substantial evidence indicated PEEK-OPTIMA Rods were technologically and physically similar to other Class II rigid pedicle systems, not the Class III dynamic stabilization system devices, in which the device had previously been grouped. As a result of the device design and material properties, PEEK-OPTIMA Rods maintain interpedicular distance, eliminating compression and elasticity often found in Class III dynamic stabilization systems. Furthermore, the predominant indication for use as an adjunct to spinal fusion, not dynamic stabilization, offered a new context for reclassification. Several clinical publications have reported high fusion rates, low re-operation rates due to adjacent segment disease and good to excellent clinical outcome scores with PEEK Rods.[1-5]

FDA Reclassification Ruling

The FDA issued a final ruling on December 29, 2016, crediting all stakeholders who contributed to this effort.

Under the final ruling:

1. Pedicle screw systems, including PEEK-OPTIMA polymer-based rods, when used as an adjunct to spinal fusion procedures are:
   a. Reclassified from Class III to Class II devices.
   b. Renamed "thoracolumbosacral pedicle screw systems."
2. Dynamic stabilization systems, when used as an adjunct to fusion are:
   a. Reclassified from Class III to Class II devices with special controls.
   b. Renamed "semi-rigid systems". PEEK-OPTIMA polymer-based rods are included in this sub-type.
3. Thoracolumbosacral pedicle screw systems will be more precisely defined to delineate between rigid and semi-rigid systems.

The FDA also indicated that device technology, like Invibio PEEK-OPTIMA Rods, could fit the new semi-ridged system product class, but would require clinical performance data supporting clear and adequate technological evaluation. Data would need to be representative of design and footprints, correspond to the product being submitted for FDA 510(k) clearance, and along with other Class II general and special controls, provide a reasonable assurance of semi-rigid system safety and effectiveness.

Under the reclassification, manufacturers of current marketed semi-rigid systems, for all indications for use, must submit a 510(k) amendment and comply with ruling-defined special controls by June 30, 2019. To that end, Invibio will enlist a sponsor to assist with obtaining 510(k) clearances for its newly named Class II device, the PEEK-OPTIMA Spinal Rods for spinal lumbar fusion.

The FDA also suggested a continued industry-wide collaboration in eventually removing the clinical data requirement. Doing so would make the 510(k) clearance for Class II semi-rigid devices even more timely and efficient, and foster further technological innovation. That's good news for manufacturers and patients alike. ▲

Why Metal Rod Alternatives Are Necessary

Spinal rods composed of metal are not without challenges, including, but not limited to, rod breakage, screw loosening, and accelerated degeneration at adjacent spinal segments. The high stiffness inherent in all-metal constructs is believed to contribute to these clinical challenges and negatively impact patient outcomes.[6-7] In addition, metals like titanium lack artifact-free imaging, which impacts a surgeon's ability to assess posterior decompression and fusion post-operatively.

Semi-Rigid Rods May Bridge Treatment Gap

PEEK-OPTIMA Spinal Rods offer a polymer-based stabilization. The material exhibits sufficient strength to reduce the range of motion[7-8] and stabilize the treated segment.[9] And, with a modulus similar to cortical bone, PEEK still permits physiological movement on adjacent upper and lower segments.[8] As a result, clinical results increasingly suggest that PEEK-OPTIMA Spinal Rod components preserve or slow down the degeneration of adjacent discs.[3] Consequently, patients may benefit from improved load sharing that encourages fusion,[7,10-11] and more physiologic loading at adjacent levels, which may decelerate degeneration.[1,12]

ABOUT THE AUTHOR

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Craig Valentine is the Director of Quality and Regulatory Affairs for Invibio Biomaterial Solutions. Having graduated from the University of Wales at Cardiff in Polymer Chemistry and Technology, Craig moved to the United States, where he spent 12 years in various technical and R&D roles. In 2007 he moved back to his native England to join Invibio. In his present role, Craig oversees Quality Assurance, Compliance and accreditation for Invibio. In addition, he leads the global RA support team and all product registration activities.

Further information on the final ruling can be found at "Orthopedic Devices; Reclassification of Pedicle Screw Systems, Henceforth To Be Known as Thoracolumbosacral Pedicle Systems, Including Semi-Rigid Systems."

For more information on Invibio PEEK-OPTIMA Rods, please visit https://invibio.com/

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