Vy Spine Announces FDA Clearance of 3D Printed LumiVy OsteoVy PEKK Lumbar IBF

Bountiful, UT – October 9, 2024—Vy Spine, a spine innovation leader using differentiated materials and designs, announced today that it has received U.S. Food and Drug Administration (FDA) clearance for its LumiVy OsteoVy PEKK Lumbar IBF.

The device is indicated for intervertebral body fusion for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. The LumiVy OsteoVy PEKK Lumbar IBF combines the osseointegration properties of the 3D printed OXPEKK material and the novel OsteoVy lattice structure unique to Vy Spine.

The LumiVy OsteoVy PEKK Lumbar IBF is offered in numerous footprints and heights, ranging from 6mm to 21mm addressing a full range of lumbar interbody approaches including anterior, oblique anterior, lateral, oblique posterior, posterior, and transforaminal. Additionally, the LumiVy OsteoVy PEKK Lumbar IBF implants are available in a range of lordosis, and hyperlordosis. The LumiVy Lumbar IBF System also features IBF-S implants, which have self-drilling screws to aid in anchoring the device directly to the bone.

OXPEKK has demonstrated bone ingrowth, no radiographic interference, no fibrotic tissue membrane formation, a significant increase in bony apposition over time, and significantly higher push-out strength compared to standard PEEK. In addition to these product benefits, OXPEKK is bacterostatic and an ideal option for patients with metal hypersensitivity. Vy Spine's proprietary OsteoVy lattice structure aids in bony integration as well as wicking, PEKK being a hydrophilic material, to provide even greater benefit as an interbody implant.

"The LumiVy OsteoVy PEKK Lumbar IBF clearance is another product in a long line of Vy Spine implants which will utilize the unique qualities of our proprietary OsteoVy PEKK designs," said Bret Berry, President of Product Development for Vy Spine. "As we researched OXPEKK and its unique characteristics, we found that this composition accomplishes what PEEK cannot. We are excited about the OXPEKK material and our continued partnership with Oxford Performance Materials."

"We are thrilled that Vy Spine has reached this important milestone with its second OsteoFab product approval," said Scott DeFelice, CEO of Oxford Performance Materials. "We are confident that the combination of OPM's novel 3D printed PEKK technology and Vy Spine's unique designs & experience within the spine marketplace will drive substantial adoption of this best-in-class solution."

About Vy Spine, LLC.

VySpine was created through active internal development and the licensing of various proven technologies using innovative materials and designs. The company strives to outpace the competition by collaborating with key spine innovators while providing a flexible, cost-effective approach to spine care. Learn more at www.vyspine.com

About Oxford Performance Materials, Inc.

Founded in 2000, Oxford Performance Materials (OPM) is a pioneer in the development and commercialization of advanced materials and additive manufacturing technologies. OPM's proprietary OsteoFab technology leverages the high-performance PEKK (poly-ether-ketone-ketone) polymer and state-of-the-art 3D printing experience to produce devices that address critical challenges in today's orthopedic industry. OPM provides the world's only implantable medical devices that are personalized, metal-free, osseointegrative, anti-bacterial, radiolucent, and fully modifiable in the operating room. OPM is in commercial production of numerous orthopedic implant applications, including lower & upper extremity, oncology, trauma, cranial, facial, spinal, and sports medicine devices. OPM has also developed patented PEKK nanocoating technologies to improve performance of metal implants.

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