MCRA Assists Curiteva Inc. with FDA 510(k) Clearance for Inspire 3D Printed Trabecular PEEK Lumbar Interbody Fusion System

Client Need

Curiteva is a privately held technology and manufacturing company dedicated to advancing spine surgery and improving clinical outcomes by partnering with providers and suppliers to deliver innovative and intuitive implant systems to the market. Curiteva engaged MCRA to support its FDA clearance preparations for their Inspire 3D Printed Trabecular PEEK Lumbar Interbody Fusion System.

"Working with MCRA as a strategic partner to advance our regulatory portfolio utilizing our transformative porous PEEK technology was critical in the rapid achievement of our recent FDA 510(k) clearance. Due to the collaborative efforts of the MCRA and Curiteva teams, the comprehensive 510(k) review process took less than 60 days from submission to clearance - a remarkable achievement. The professional acumen exhibited by the regulatory group at MCRA is a primary reason they continue to be a powerhouse in the industry."

Eric Linder, Founder & Chief Technology Officer, Curiteva

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MCRA Approach

Curiteva partnered with MCRA previously on Inspire Trabecular PEEK Cervical Interbody Fusion System in February 2023, which also received FDA clearance. MCRA's Spine Regulatory team engaged with Curiteva for the Inspire 3D Printed Trabecular PEEK Lumbar Interbody Fusion System for use in anterior, transforaminal, posterior, and lateral lumbar interbody fusion procedures. MCRA worked with Curiteva to implement strategies to address complex biomechanics, manufacturing, and biocompatibility to ensure a novel device in the lumbar spine could be substantially equivalent to the predicate landscape.

MCRA THERAPY: Spine

MCRA SERVICES: US Regulatory

Outcome

The project utilized MCRA's strategic regulatory expertise to navigate the FDA's questions and testing requirements, resulting in FDA 510(k) clearance for the device.