

MCRA Supports 3D Systems with 510(k) FDA Clearance for VSP PEEK Cranial Implant Device

Client Need

3D Systems' solutions address a variety of advanced applications in healthcare and industrial markets such as medical and dental, aerospace & defense, automotive, and durable goods. 3D Systems engaged MCRA for regulatory support with their FDA submission for VSP PEEK Cranial Implant.

"This achievement reflects our commitment to advancing patient care through innovative solutions. Our successful partnership with MCRA was crucial in navigating the regulatory process, particularly with their expert guidance on biocompatibility. Working with MCRA has been a highly professional and productive experience, and their support was instrumental in achieving this important milestone."

**Ashely Dawson PhD, Director,
Regulatory Affairs at 3D Systems**

MCRA Approach

MCRA's best in class biocompatibility team worked with 3D Systems to design and execute a biocompatibility strategy, including chemical characterization studies, that addressed FDA expectations and demonstrated that the device is biocompatible for patient use.

MCRA THERAPY: Neurology

MCRA SERVICES: US Regulatory and Biocompatibility

Outcome

The VSP PEEK Cranial Implant is now the world's first patient-specific and 3D-printed PEEK cranial implant using an extrusion platform to receive FDA clearance.

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