

MCRA Partner Orthobond Granted De Novo for Innovative Pedicle Screw System with Ostaguard™ Coating

Client Need

Orthobond Corporation is a surface technology company that has developed proprietary antibacterial surfaces, with broad applications in the medical device industry and beyond. Orthobond engaged MCRA in March 2020 to help support their pre-submission efforts in gaining FDA feedback to their regulatory pathway and proposed performance testing suite for their Ostaguard antibacterial technology.



"Having worked with MCRA on other first-to-market technologies, I knew they would be the right partner for Orthobond when we began the De Novo process for our antibacterial surface technology, Ostaguard. MCRA possesses the breadth and depth of talent necessary to not only deal with the regulatory plans and overall strategy, but the critical daily tactics such as regulatory research, documentation and writing. What MCRA brings to a project like this is a diversely talented team focused on ensuring a submission of this magnitude is done with expertise."

David Nichols, CEO, Orthobond

MCRA Approach

MCRA's Spine team developed the regulatory strategy with subsequent pre-submissions and supported Orthobond through the entirety of the FDA process and submitted the De Novo on Orthobond's behalf.

MCRA THERAPY: Spine

MCRA SERVICES: US Regulatory

Outcome

On April 5th 2024, the FDA granted a De Novo for the Ostaguard antibacterial coating on the SeaSpine Mariner Pedicle Screw System for commercial use.

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