

# MCRA Supports Onkos Surgical with First FDA De Novo Approval for Antibacterial Coating for Implants

## Client Need

Onkos Surgical is a leader in innovative solutions for musculoskeletal oncology and complex orthopedic conditions. Onkos Surgical engaged MCRA in December of 2020 to support its De Novo preparations for their antibacterial coating for tumor and revision orthopedic implants.



“The De Novo authorization of the Onkos antibacterial technology is a significant milestone on a long, collaborative journey with the FDA. A great deal of in-depth and first-of-its-kind science and engineering provided the body of evidence for this authorization, opening the door for further advancements with this technology. We are very thankful to MCRA for advising us and providing expert guidance on scientific as well as regulatory planning.”

**Gene Kulesha, Executive Director  
at Onkos Surgical**

## MCRA Approach

MCRA's Regulatory and Biocompatibility teams worked jointly to provide strategic support on the De Novo submission planning, technical information and test report review. MCRA worked diligently with Onkos to draft the initial and supplementary De Novo submissions, as well as manage FDA correspondence, interactive review questions, labeling, and finalization of the De Novo grant.

**MCRA THERAPY:** Orthopedics

**MCRA SERVICES:** US Regulatory and Biocompatibility

## Outcome

In April 2024 the FDA granted the De Novo application for commercial use of the implants.

