MCRA Supports BONESUPPORT with FDA De Novo Clearance and Reimbursement Strategy for CERAMENT G

Client Need

BONESUPPORT came to MCRA in need of US Regulatory and reimbursement strategy support for their De Novo for the combination product, CERAMENT G.

"We've worked with MCRA since 2016. MCRA's integrated service divisions have been very helpful and supportive in providing valuable strategic guidance and project support to BONESUPPORT since that time. I have been extremely happy with our decision to work with MCRA in support of our US Regulatory needs which is evidenced by this De Novo achievement. We also appreciate the integrated role of the statistical experts from Biomedical Statistical Consulting in performing the analyses of our clinical data."
Emil Billback, CEO, BONESUPPORT

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MCRA Approach

MCRA's assisted BONESUPPORT with developing the US Regulatory strategy that involved the De Novo pathway, which had recently become available for combination products. To successfully navigate the De Novo, there were numerous discussions and negotiations with FDA required to bring the process to a successful resolution. In addition, BONESUPPORT wanted to take advantage of the benefits of its Breakthrough Device Designation for CERAMENT G for its reimbursement strategy to qualify for Medicare new-technology payments.

MCRA THERAPY: Orthopedic

MCRA SERVICES: US Regulatory & Reimbursement

Outcome

BONESUPPORT was the first to receive De Novo clearance for a drug/device combination product. BONESUPPORT also received approval for Medicare's New-Technology Add-On Payment (NTAP) for inpatient cases and Transitional Pass-Through (TPT) Payment for hospital outpatient cases. Both provide additional payment amounts in addition to the standard payments that make hospitals much more likely to adopt products at launch.