MCRA Assists KeriMedical SA with Pre-Market Authorization Approval of Breakthrough Device, TOUCH® CMC1 Prosthesis

Client Need

KeriMedical SA approached MCRA in 2020 for support with reviewing their testing plan and regulatory strategy of the TOUCH® CMC1 Prosthesis. The MCRA regulatory team jumped right in and provided KeriMedical SA with guidance on their regulatory submission strategy, including breakthrough device designation and Sprint Discussion submissions, ultimately leading to a premarket approval (PMA) approval of the 1st dual mobility thumb carpometacarpal prosthesis in the U.S.

MCRA Approach

MCRA's integrated teams, regulatory, orthopedic, clinical, biocompatibility, biostatistics, reimbursement and quality assurance, worked together to provide KeriMedical with a comprehensive U.S. regulatory strategy through years of development. MCRA's regulatory team advised on developing the TOUCH® strategy throughout multiple sprint discussions, inclusive of non-clinical, biocompatibility, and clinical study designs, some of which required systematic literature review and technical justifications to support negotiations with FDA. They also served as the liaison between the clinical site and the statisticians to analyze and report the positive, clinical study outcomes.

MCRA supported Keri Medical to author and submit the TOUCH® PMA, then addressing FDA's questions during the the review with a creative and realistic approach, resulting in approval. MCRA's Regulatory, Clinical, Biostatistics, Orthopedic, Biocompatibility, Clinical and Reimbursement teams navigated post-approval study negotiations.

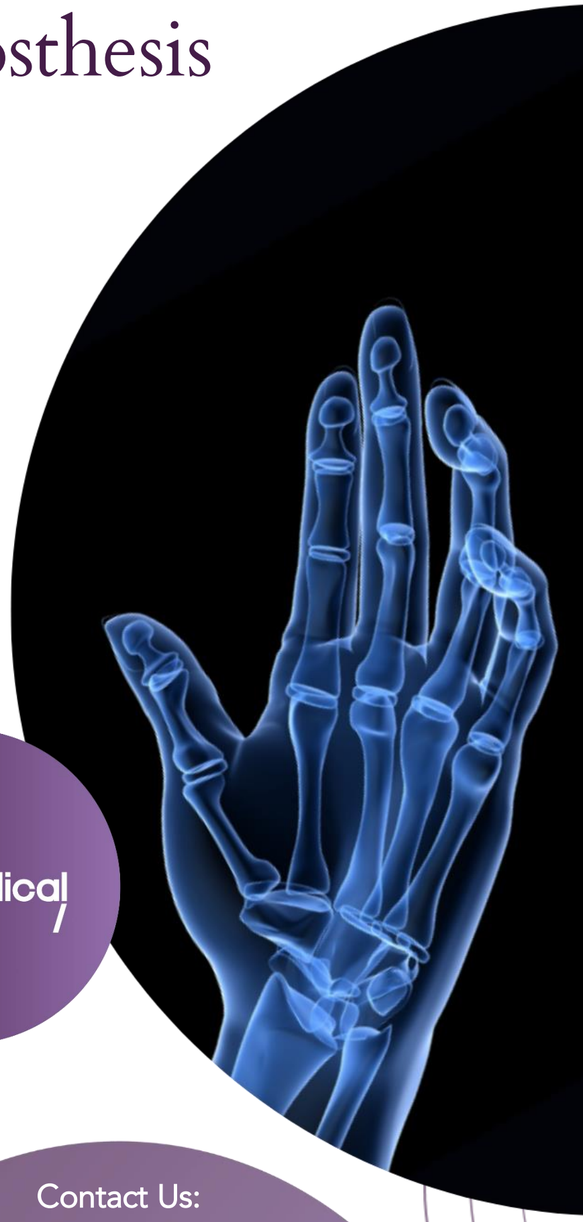
MCRA THERAPY: Orthopedics

MCRA SERVICES: US Regulatory, Clinical, Quality Assurance, Biostatistics, Biocompatibility & Reimbursement

Outcome

MCRA's extensive knowledge of the orthopedic joint arthroplasty space combined with its integrated service offerings led to a successful PMA approval for the TOUCH® CMC1 Prosthesis.

"KeriMedical SA had the opportunity to work with various integrated teams at MCRA which eventually led to the success of our TOUCH CMC 1 Prosthesis PMA approval. The MCRA team was extremely knowledgeable and reliable through the entirety of the PMA process with FDA. We look forward to continuing our partnership with MCRA during our post market approval study."
Deborah Caux, Clinical Affairs Manager, KeriMedical



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