MCRA Leads the Way: Empowering Synergy Spine Solutions with Comprehensive Regulatory, Clinical, and Healthcare Compliance Solutions Worldwide

Client Need

Synergy Spine Solutions, a company focused on artificial cervical disc replacement, engaged MCRA for assistance with their Synergy Disc.



"MCRA has been a great partner to Synergy Spine Solutions and has been helping us navigate the US regulatory pathway needed to bring our cervical disc to market. MCRA's regulatory team has been guiding our interactions with the FDA, while MCRA's clinical team is working with us to manage our US IDE trials and EU PMCF trials. With MCRA's clinical team help in managing our studies, we have been able to continue expanding our global commercial success through surgeon outreach and new market exploration for the Synergy disc."

Jane Jacob, VP, Research and Clinical Affairs at Synergy Spine Solutions

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MCRA Approach

MCRA's regulatory, clinical, reimbursement and healthcare compliance teams collaborated closely together to design and manage the clinical studies for Synergy's 1 level and 2 level cervical discs.

MCRA's GDPR Compliance Team assisted Synergy with ensuring they were able to work in-line with European Privacy laws when conducting research in the EEA.

MCRA THERAPY: Spine

MCRA SERVICES: Regulatory, Clinical, Reimbursement and Healthcare Compliance

Outcome

Synergy Spine was able to seamlessly continue with the study requirements whilst MCRA handled the very complex world of GDPR in various countries, simultaneously working on regulatory, clinical, reimbursement strategies.

