MCRA Assists ReGelTec with IDE Approval for HYDRAFIL, the First Pivotal US Clinical Trial Approved for Nucleus Pulposus Augmentation

Client Need

ReGelTec, a medical device company focused on minimally invasive solutions of chronic low back pain from degenerative disc disease, engaged with MCRA for assistance to bring HYDRAFIL to market.

"We initially started working with MCRA based on their reputation and experience in regulatory consulting with spine technologies, but it was their team of biocompatibility experts who ultimately helped us address FDA questions and secure IDE approval. We are thrilled to initiate our clinical investigation of our breakthrough device, HYDRAFIL, in the United States."

Peter Boyd, Vice President, Business Development, ReGelTec

MCRA Approach

Over the course of several years, MCRA's regulatory and biocompatibility teams worked closely with ReGelTec to navigate FDA's strict biocompatibility requirements to design novel test methods suitable for the novel HYDRAFIL device and indication. MCRA's regulatory team also assisted the company with breakthrough, clinical study design, and IDE development.

MCRA THERAPY: Spine

MCRA SERVICES: Regulatory

Outcome

MCRA assisted ReGelTec with obtaining IDE approval for a study designed with primary endpoint evaluated at 1 year.

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