MCRA Assists Empirical Spine with Pre-Market Approval of Breakthrough Device, LimiFlex Dynamic Sagittal Tether

Client Need

Empirical Spine approached MCRA prior to study enrollment for regulatory strategy and clinical study support. Since then, MCRA has assisted Empirical Spine with all IDE regulatory activities, breakthrough device designation, CEC management, clinical trial support, modular PMA submission, and related FDA interactions, ultimately leading to premarket approval (PMA) of a novel motion-preserving spinal implant that is intended to provide dynamic flexion-restricting stabilization of the spine following a lumbar decompression.

"MCRA has been our partner on this PMA since the beginning of the trial. From clinical trial enrollment, including through COVID, to our modular PMA submission process, MCRA's insight and relationships with the FDA review team were key to our regulatory strategy and success."

Louie Fielding, Co-Founder and COO, Empirical Spine

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MCRA Approach

MCRA's integrated regulatory, biocompatibility, safety management, and clinical teams worked together to provide Empirical Spine with IDE support, comprehensive regulatory strategy and PMA submission services. MCRA's regulatory team served as a partner to Empirical Spine throughout their journey, bringing in experts in biocompatibility, safety management, clinical research, quality assurance, and other subject matter areas as needed, allowing the lean Empirical Spine team to receive the right support when it mattered most.

MCRA THERAPY: Spine

MCRA SERVICES: US Regulatory, Clinical, Biocompatibility, Safety Management

Outcome

MCRA's expertise in spine PMAs combined with its integrated service offerings led to a successful PMA approval for the LimiFlex Dynamic Sagittal Tether.

Margeaux Rogers, Vice President, Regulatory Affairs at MCRA states, "MCRA's integrated team of experts allowed us to be the right partner for Empirical Spine throughout their IDE and PMA journey. By giving them access to our deep bench of specialists exactly when they needed it, we helped them navigate the most complex regulatory pathway in the U.S. for medical devices, while enabling them to maintain a lean and efficient sponsor team. It is especially rewarding to help small companies bring meaningful innovation to patients, and Empirical Spine's success is a testament to that mission."