MCRA Assists Epiminder with FDA De Novo Approval for Minder, the First Implantable, Continuous EEG Monitor for Epilepsy

Client Need

Epiminder is an Australian medical device company. Their focus is developing an implantable device for continuous and remote monitoring of brain activity in persons with epilepsy. They engaged MCRA for multiple services and leadership to develop their FDA Breakthrough Designation and De Novo requests to bring this first-of-a-kind device to the United States.

"Epiminder's management is very pleased to have chosen MCRA for its leadership and highly-specialized regulatory and scientific expertise. MCRA leadership produced flawless integration of Epiminder and MCRA experts to answer FDA questions during review and granting of our breakthrough designation and De Novo requests. I can't imagine a better partner and guide for development of our studies and collaboration with FDA to bring Minder to the United States."

Rohan Hoare, CEO at Epiminder

MCRA Approach

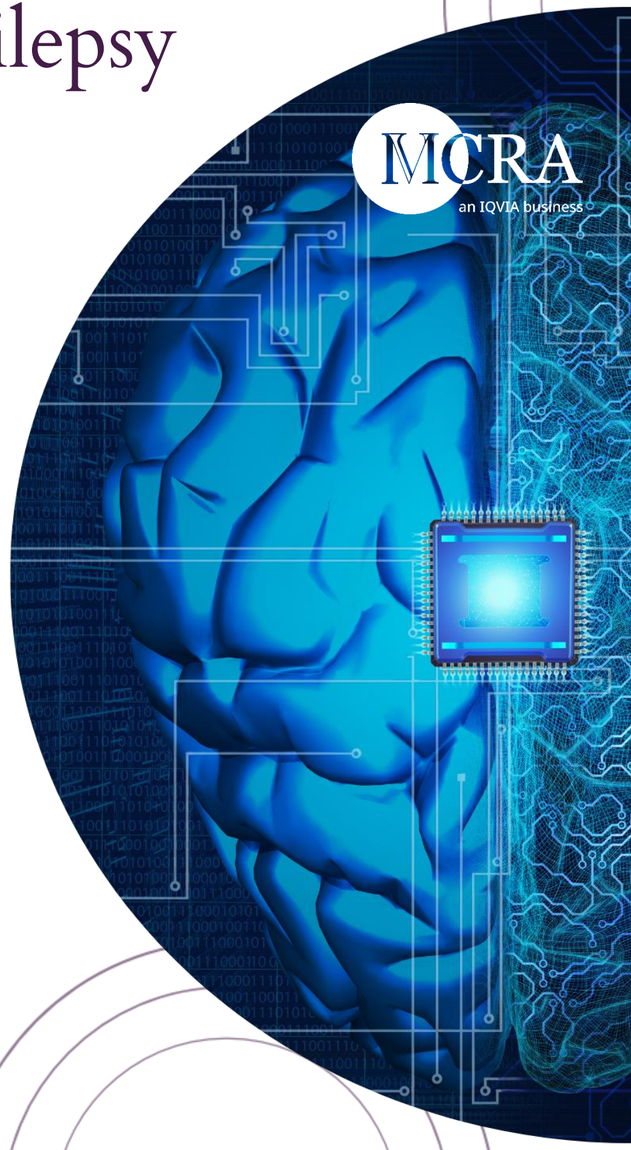
MCRA's John Doucet led broad and diverse Epiminder and MCRA Teams of subject matter experts in strategy and development of all written and verbal interactions with FDA from beginning of engagement, development and granting of breakthrough designation, development and granting of De Novo request.

MCRA THERAPY: Neurology

MCRA SERVICES: US Regulatory, Biocompatibility, and Clinical Data Analysis

Outcome

In April 2023 the FDA granted Breakthrough Designation for Minder and in April 2025 the FDA granted the De Novo request for Minder.



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