



MCRA Assists Australian Company Epiminder with FDA Breakthrough

Designation for Epilepsy Monitoring Technology



MCRA's Neurology Team, led by John Doucet, assisted Epiminder with developing the strategy for the breakthrough designation request and writing the breakthrough designation request. Dr. Doucet also played a key role in developing responses to FDA's request for additional information during the review. With this work, MCRA was a key player on the Epiminder Team responsible for obtaining this crucial FDA designation.

MCRA's Neurology Team and Dr. Doucet are continuing to lead the ongoing efforts to work with the FDA and obtain marketing authorization for the Epiminder device.

25+

Former FDA Officials

MCRA's Talent Unlocks
Your Company's
Potential
US REGULATORY

30+

Countries

Regulatory Success Including EU MDR & Japan GLOBAL REGULATORY



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