MCRA Supports Darmiyan with FDA Approval for BrainSee Device

Client Need

Darmiyan is a pioneering brain technology (deep-tech) company in San Francisco, California, focused on developing innovative and rapidly scalable products for brain health screening and monitoring. Darmiyan retained MCRA in 2021 for its broad and deep experience in Neurology, Digital Health, and Artificial Intelligence (AI).

"Darmiyan feels extremely fortunate to have partnered with MCRA to support our successful FDA submissions. The FDA Breakthrough Device Designation for BrainSee was a critical foundation for FDA collaborations during development, review, and granting of the De Novo request. MCRA is truly unique to have world-class scientific and regulatory expertise in Neurology, Digital Health, and AI that are needed to guide novel and ground-breaking devices like BrainSee through the FDA review process. MCRA's level of support spanned the entire spectrum and included leading our interactions with FDA, collaborating on development of test protocols, and assistance with writing the submissions."

Kaveh Vejdani, Co-founder, Chief Medical & Technology Officer at Darmiyan

MCRA Approach

MCRA's team of regulatory experts collaborated closely with Darmiyan to achieve a Breakthrough Device Designation for BrainSee in 2021, develop the evidence and strategy for submission of a De Novo request in 2022. MCRA also assisted with collecting data and provided data management for the client.

MCRA THERAPY: Neurology, Digital Health

MCRA SERVICES: Digital Health, AI & Imaging Center, US Regulatory

Outcome

MCRA helped Darmiyan obtain Breakthrough Device Designation in 2021 and navigate the rigorous FDA review process to secure granting of the De Novo request from FDA in January 2024.

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