

Fasikl Receives FDA Clearance for Felix NeuroAI™ Wristband, the First and Only AI-Powered Treatment for Essential Tremor

Client Need

Fasikl, Inc. is a pioneering neuro-AI company dedicated to developing advanced, AI-powered neural technologies. Fasikl have developed a groundbreaking approach that integrates cloud-based AI with neurostimulation to aid in the treatment of upper limb essential tremor. MCRA was engaged for multiple services to support the development of their 510(k) for the Felix NeuroAI™ Wristband, a first-of-its-kind noninvasive, drug-free alternative to surgery and medications, providing all-day relief for adults living with essential tremor.

“Essential tremor affects approximately 7 million people in the U.S., yet treatment options remain limited. MCRA was a critical partner in our 510(k) clearance journey, serving as a “one-stop shop” for development and regulatory support. Their expertise in EMC, biocompatibility, AI, software, and regulatory affairs proved invaluable. Through careful planning, rigorous preparation, and structured FDA interactions, we achieved 510(k) clearance of Felix on schedule.”

**Zhen Zhang, President
Fasikl, Inc.**

MCRA Approach

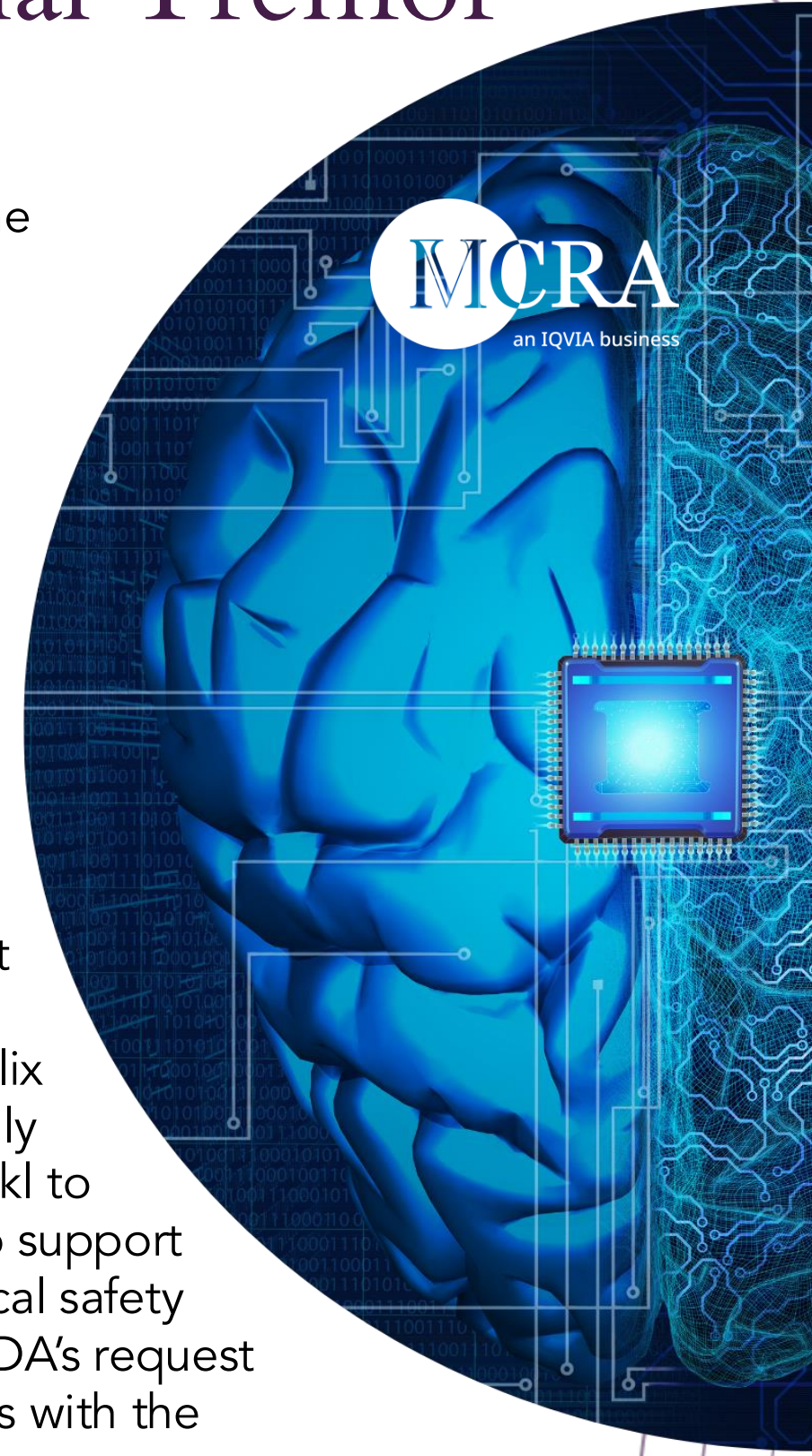
MCRA helped Fasikl receive 510(k) clearance for the Felix NeuroAI™ Wristband.

MCRA THERAPY: Neurology

MCRA SERVICES: US Regulatory and Biocompatibility, Digital Health

Outcome

MCRA's Devjani Saha led a team of broad and diverse subject matter experts from Fasikl and MCRA to complete the 510(k) process. MCRA worked with Fasikl to develop a strategy to present their AI algorithm and the clinical evidence to support not only safety and effectiveness of the Felix NeuroAI™ Wristband but also demonstrate clinically meaningful results. MCRA worked closely with Fasikl to develop the documentation and testing needed to support the 510(k), advised Fasikl on their EMC and electrical safety testing approach, and helped draft responses to FDA's request for additional information. MCRA also led meetings with the FDA to discuss the clinical trial findings.



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