FDA 510(k) Premarket Notification

CLEARED

K222983 NeuroBlate Fusion-S Software V3.17

Mar 15, 2023
168 days to decision

K222983 · Product code: **GEX** · Neurology
Source: https://www.510kdatabase.net/k222983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 28, 2022
Decision date	Mar 15, 2023
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Monteris Medical,**
Location	Alameda, CA, US
Contact	David H Mueller
Website	https://www.monteris.com
510(k) history	12 submissions · 12 cleared · 2009-2026

Monteris Medical is a leader in minimally invasive laser ablation technology for the brain. The company develops and markets the NeuroBlate® System, a robotic, MR-guided laser interstitial thermal therapy (LITT) platform designed for neurosurgical applications. Monteris operates with a manufacturing facility in Alameda, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2009. Monteris specializes in neurology devices, with a focus on thermal ablation systems for brain tumors, radiation necrosis, and drug-resistant epilep...