

K193375 NeuroBlate SystemJan 3, 2020
29 days to decisionK193375 · Product code: **GEX** · Neurology
Source: <https://www.510kdatabase.net/k193375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 5, 2019
Decision date	Jan 3, 2020
Days to decision	29 days
Third-party review	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...

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