

K231061 NeuroBlate SystemDec 8, 2023
239 days to decisionK231061 · Product code: **GEX** · Neurology
Source: <https://www.510kdatabase.net/k231061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 13, 2023
Decision date	Dec 8, 2023
Days to decision	239 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
510(k) history	12 submissions · 12 cleared · 2009-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231061/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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