

**K201056 NeuroBlate System**Aug 21, 2020  
122 days to decisionK201056 · Product code: **GEX** · Neurology  
Source: <https://www.510kdatabase.net/k201056/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 21, 2020
Decision date	Aug 21, 2020
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Monteris Medical, Inc.</b>
Location	Winnipeg, Mb, CA
Contact	David H. Mueller
510(k) history	8 submissions · 8 cleared · 2011-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201056/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026