

**K162762 NeuroBlate System**Oct 26, 2016  
26 days to decisionK162762 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162762/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Special                                 |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Sep 30, 2016                            |
| Decision date         | Oct 26, 2016                            |
| Days to decision      | 26 days                                 |
| Third-party review    | 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/k162762/> 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