

**K230819 OmniGuide RFID Surgical Laser Fibers**Apr 21, 2023  
28 days to decisionK230819 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230819/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 24, 2023
Decision date	Apr 21, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omni-Guide Holdings, Inc.</b>
Location	Billerica, MA, US
Contact	Carlos O Acosta
510(k) history	2 submissions · 2 cleared · 2022-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230819/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026