

K203241 OmniGuide BeamPath OTO-U FiberJan 14, 2021
72 days to decisionK203241 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203241/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 3, 2020
Decision date	Jan 14, 2021
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Omniguide, Inc.
Location	Cambridge, MA, US
Contact	David Johnson
Website	http://www.omni-guide.com
510(k) history	14 submissions · 14 cleared · 2006-2021

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