

K183199 TRIO HandpieceMay 2, 2019
164 days to decisionK183199 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 19, 2018
Decision date	May 2, 2019
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183199/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026