

K081939 OMNIGUIDE BEAMPATH FIBER OPTIC HANDPIECE SYSTEM AND STERILIZATION TRAYAug 12, 2008
35 days to decisionK081939 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k081939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 8, 2008
Decision date	Aug 12, 2008
Days to decision	35 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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