FDA 510(k) Premarket Notification

K004006 SELECTA 7000 FREQUENCY DOUBLED, Q-SWITCHED ND:YAG OPHTHALMIC LASER

CLEARED

Mar 26, 2001
90 days to decision

K004006 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k004006/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 26, 2000
Decision date	Mar 26, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lumenis, Inc.**
Location	Mchenry, IL, US
Contact	KAREN BAKER
510(k) history	43 submissions · 43 cleared · 1979-2022

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k004006/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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