

K003318 PHOTON MULTI-PLATFORM SYSTEM, MODEL Z-12834-X & Z-13175-X

May 22, 2001
210 days to decision

K003318 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k003318/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 24, 2000
Decision date	May 22, 2001
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paradigm Medical Industries, Inc.
Location	Salt Lake City, UT, US
Contact	TRACY S BEST
510(k) history	10 submissions · 10 cleared · 1995-2005

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k003318/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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