FDA 510(k) Premarket Notification

K121938 MEDILAS H RFID LASER FIBER

CLEARED

Aug 1, 2012
30 days to decision

K121938 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k121938/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 2, 2012
Decision date	Aug 1, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dornier Medtech America, Inc.**
Location	Marietta, GA, US
Contact	JOHN HOFFER
510(k) history	40 submissions · 40 cleared · 1990-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k121938/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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