FDA 510(k) Premarket Notification

CLEARED

K080959 DORNIER MEDILAS D 30 LASER, MEDILAS D 1064

Jun 27, 2008
85 days to decision

K080959 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k080959/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 3, 2008
Decision date	Jun 27, 2008
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k080959/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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