FDA 510(k) Premarket Notification

K130344 DORNIER MEDILAS UROPULSE

CLEARED

Mar 21, 2013
38 days to decision

K130344 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k130344/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 11, 2013
Decision date	Mar 21, 2013
Days to decision	38 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