FDA 510(k) Premarket Notification

K011322 DORNIER SAPPHIREERBIUM HANDPIECE, DORNIER SAPPHIRESPOT HANDPIECE

CLEARED

Nov 19, 2001
202 days to decision

K011322 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k011322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 1, 2001
Decision date	Nov 19, 2001
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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