FDA 510(k) Premarket Notification

K003993 DORNIER MEDILAS D SKINPULSE LASER SYSTEM (SKINPULSE)

CLEARED

Mar 26, 2001
90 days to decision

K003993 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k003993/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 26, 2000
Decision date	Mar 26, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dornier Surgical Products, Inc.**
Location	Phoenix, AZ, US
Contact	WALTER PAYERL
510(k) history	9 submissions · 9 cleared · 1998-2001