FDA 510(k) Premarket Notification

K981438 DORNIER MEDILAS E

CLEARED

Jul 20, 1998
90 days to decision

K981438 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k981438/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 21, 1998
Decision date	Jul 20, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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