FDA 510(k) Premarket Notification

K012682 REPROCESSED LASER PROBE

CLEARED

Nov 8, 2001
86 days to decision

K012682 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k012682/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 14, 2001
Decision date	Nov 8, 2001
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sterilmed, Inc.**
Location	Plymouth, MN, US
Contact	PATRICK FLEISCHHACKER
510(k) history	64 submissions · 64 cleared · 2001-2024