FDA 510(k) Premarket Notification

K002032 C02 LASER MULTIPULSE

CLEARED

Sep 11, 2000
70 days to decision

K002032 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k002032/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 3, 2000
Decision date	Sep 11, 2000
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Asclepion-Meditec AG**
Location	Irvine, CA, US
Contact	WILLIAM KELLEY
510(k) history	5 submissions · 5 cleared · 2000-2002