FDA 510(k) Premarket Notification

K992298 IRIDERM, MODEL APEX 800

CLEARED

Dec 9, 1999
154 days to decision

K992298 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k992298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 8, 1999
Decision date	Dec 9, 1999
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Iridex Corp**
Location	Mountain View, CA, US
Contact	BRAD RENTON
510(k) history	13 submissions · 13 cleared · 1998-2012