FDA 510(k) Premarket Notification

K982031 OCULIGHT GL WITH THE DERMATOLOGY HANDPIECE

CLEARED

Sep 8, 1998
90 days to decision

K982031 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k982031/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 10, 1998
Decision date	Sep 8, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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