FDA 510(k) Premarket Notification

K062369 IRIDEX OCULIGHT TX

CLEARED

Nov 8, 2006
86 days to decision

K062369 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k062369/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 14, 2006
Decision date	Nov 8, 2006
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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