FDA 510(k) Premarket Notification

K060372 INTRALASE FS LASER, INTRALASE FS30 LASER, MODELS 1, 2, 3

CLEARED

Aug 16, 2006
184 days to decision

K060372 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k060372/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 13, 2006
Decision date	Aug 16, 2006
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Intra Lase Corp.**
Location	Irvine, CA, US
Contact	CHARLINE GAUTHIER
510(k) history	9 submissions · 9 cleared · 1999-2008