FDA 510(k) Premarket Notification

K113390 LASER INDIRECT OPHTHALMOSCOPE 500(LIO-500)

CLEARED

Feb 14, 2012
90 days to decision

K113390 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k113390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 16, 2011
Decision date	Feb 14, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Meridian AG**
Location	Thun, Bern, CH
Contact	Kevin Walls
510(k) history	6 submissions · 6 cleared · 2002-2024