FDA 510(k) Premarket Notification

K041721 LVI AESTHETIC LASER

CLEARED

Aug 5, 2004
42 days to decision

K041721 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k041721/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 24, 2004
Decision date	Aug 5, 2004
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hoya Photonics, Inc.**
Location	Fremont, CA, US
Contact	JIM GREEN
510(k) history	5 submissions · 5 cleared · 2004-2010