FDA 510(k) Premarket Notification

K080248 SPECTRA VRMIII Q-SWITCHED ND: YAG LASER SYSTEM AND DYE HANDPIECES

CLEARED

Apr 23, 2008
83 days to decision

K080248 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k080248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 31, 2008
Decision date	Apr 23, 2008
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lutronic Corporation**
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	29 submissions · 29 cleared · 2007-2025