FDA 510(k) Premarket Notification

K091320 SPECTRA SP II, SPECTRA DENTA II

CLEARED

Aug 19, 2009
106 days to decision

K091320 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k091320/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 5, 2009
Decision date	Aug 19, 2009
Days to decision	106 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