FDA 510(k) Premarket Notification

K080932 MOSAIC LASER SYSTEM

CLEARED

Jun 9, 2008
68 days to decision

K080932 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k080932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 2, 2008
Decision date	Jun 9, 2008
Days to decision	68 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