FDA 510(k) Premarket Notification

K192331 LaseMD LEO Laser System

CLEARED

Nov 12, 2019
77 days to decision

K192331 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k192331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 27, 2019
Decision date	Nov 12, 2019
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lutronic Global**
Location	Billerica, MA, US
Contact	James Childs
510(k) history	1 submissions · 1 cleared · 2019-2019