FDA 510(k) Premarket Notification

K173827 LightScalpel

CLEARED

Sep 14, 2018
270 days to decision

K173827 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k173827/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 18, 2017
Decision date	Sep 14, 2018
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lightscalpel, LLC**
Location	Woodinville, WA, US
Contact	David Walters
510(k) history	5 submissions · 5 cleared · 2012-2018