FDA 510(k) Premarket Notification

K132661 LIGHTSCALPEL

CLEARED

Jan 2, 2014
129 days to decision

K132661 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k132661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 26, 2013
Decision date	Jan 2, 2014
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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