FDA 510(k) Premarket Notification

K213669 LIGHTSCALPEL LS-4020

CLEARED

Feb 15, 2023
450 days to decision

K213669 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213669/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 22, 2021
Decision date	Feb 15, 2023
Days to decision	450 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lightscalpel, Inc.**
Location	Bothell, WA, US
Contact	David Walters
510(k) history	1 submissions · 1 cleared · 2023-2023