FDA 510(k) Premarket Notification

K182604 New Era

CLEARED

Nov 14, 2018
54 days to decision

K182604 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182604/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 21, 2018
Decision date	Nov 14, 2018
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Step UP Skin Laser, LLC**
Location	New York, NY, US
Contact	Michelle Hokama
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Law Offices of Irving L. Wiesen, P.C.**
Contact	Irving Wiesen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov