

K182604 New EraNov 14, 2018
54 days to decisionK182604 · Product code: **GEX** · General & Plastic SurgerySource: <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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026