

K181480 MMD TipAug 1, 2018
57 days to decisionK181480 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 5, 2018
Decision date	Aug 1, 2018
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Strata Skin Sciences, Inc.
Location	Horsham, PA, US
Contact	Shmuel Gov
510(k) history	2 submissions · 2 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Strata Skin Sciences, Inc. % Promedic, LLC
Contact	Paul Dryden

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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