

K193478 XTRAC Momentum Excimer Laser SystemJan 14, 2020
29 days to decisionK193478 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 16, 2019
Decision date	Jan 14, 2020
Days to decision	29 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	Chuck Mierkiewicz
510(k) history	2 submissions · 2 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Strata Skin Sciences, Inc. C/O Promedic, LLC
Contact	Paul Dryden

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

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