

K242142 Fraxel® FTX Laser SystemAug 21, 2024
30 days to decisionK242142 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 22, 2024
Decision date	Aug 21, 2024
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Solta Medical
Location	Bothell, WA, US
Contact	Sophie Xu
510(k) history	5 submissions · 5 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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/k242142/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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