

K210847 UltraClear Fractional Laser SystemDec 10, 2021
263 days to decisionK210847 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k210847/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 22, 2021
Decision date	Dec 10, 2021
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fa International, LP
Location	Lincoln, RI, US
Contact	Sharon Timberlake
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Sharon Timberlake Consulting, LLC
Contact	Sharon Timberlake

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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