

K213350 mJOULE System and AccessoriesApr 15, 2022
189 days to decisionK213350 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 8, 2021
Decision date	Apr 15, 2022
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sciton, Inc
Location	Palo Alto, CA, US
Contact	Jay Patel
510(k) history	23 submissions · 23 cleared · 2000-2025

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