

K203728 DarwinJul 14, 2021
205 days to decisionK203728 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 21, 2020
Decision date	Jul 14, 2021
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Luvo Medical Technologies, Inc.
Location	Cambridge, CA
Contact	Gregory Berzak
510(k) history	5 submissions · 5 cleared · 2020-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203728/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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