

K193446 Bare: 808Mar 10, 2020
89 days to decisionK193446 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 12, 2019
Decision date	Mar 10, 2020
Days to decision	89 days
Third-party review	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

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