

K193266 MIINJan 22, 2021
423 days to decisionK193266 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k193266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 26, 2019
Decision date	Jan 22, 2021
Days to decision	423 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medico USA, Inc.
Location	Los Angeles, CA, US
Contact	Peter Son
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Provision Consulting Group, Inc.
Contact	Joyce Kwon

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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