FDA 510(k) Premarket Notification

K193266 MIIN

CLEARED

Jan 22, 2021
423 days to decision

K193266 · 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