FDA 510(k) Premarket Notification

K203054 FlexSys

CLEARED

Mar 5, 2021
149 days to decision

K203054 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203054/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 7, 2020
Decision date	Mar 5, 2021
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gme (German Medical Engineering) GmbH**
Location	Willow Creek, MT, US
Contact	Stefan Schulze
510(k) history	6 submissions · 6 cleared · 2014-2023

REGULATORY CONSULTANT

Consulting firm	**Philosopher'S River, LLC**
Contact	Katja Kerl

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov