

K203054 FlexSysMar 5, 2021
149 days to decisionK203054 · Product code: **GEX** · General & Plastic SurgerySource: <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&apos;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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203054/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026