

**K221623 FlexSys, FlexSys UVB EPL 308 nm, FlexSys UVB EPL  
lite 308 nm, FlexSys IR 1550 nm**Mar 10, 2023  
277 days to decisionK221623 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221623/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 6, 2022
Decision date	Mar 10, 2023
Days to decision	277 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Gme (German Medical Engineering) GmbH</b>
Location	Willow Creek, MT, US
Contact	Dietmar Fischer
510(k) history	6 submissions · 6 cleared · 2014-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221623/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026