

K180518 GME LinScan Lite 808 Laser SystemJul 23, 2018
146 days to decisionK180518 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k180518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 27, 2018
Decision date	Jul 23, 2018
Days to decision	146 days
Third-party review	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

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