

K192269 TwinScan 808/755 Laser SystemNov 19, 2019
90 days to decisionK192269 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192269/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 21, 2019
Decision date	Nov 19, 2019
Days to decision	90 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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