

**K192483 MeDioStar**Mar 13, 2020  
185 days to decisionK192483 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192483/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 10, 2019
Decision date	Mar 13, 2020
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Asclepion Laser Technologies GmbH</b>
Location	Chelmsford, MA, US
Contact	Antje Katzer
510(k) history	29 submissions · 29 cleared · 2004-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192483/> 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 14, 2026