

**K201171 LEONI Laser Fibers: BareFiber Disposable, BareFiber Reusable and Endoprobe Disposable**Apr 2, 2021  
336 days to decisionK201171 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k201171/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 1, 2020
Decision date	Apr 2, 2021
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Leoni Fiber Optics, Inc.</b>
Location	Williamsburg, VA, US
Contact	Martin Trapp
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qserve Group, Us, Inc.</b>
Contact	Patsy J. Trisler

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201171/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026