

K140503 FLEXIVA SF SIDE-FIRING SINGLE-USE LASER FIBERApr 15, 2014
47 days to decisionK140503 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k140503/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 27, 2014
Decision date	Apr 15, 2014
Days to decision	47 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	JEANNE O'&TOOLE
Website	http://www.bostonscientific.com/
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140503/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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