

K100078 MODIFIED STRAIGHT FIRE LASER FIBERFeb 12, 2010
31 days to decisionK100078 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k100078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 12, 2010
Decision date	Feb 12, 2010
Days to decision	31 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	JANET A MCGRATH
Website	https://www.bostonscientific.com/
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...

REGULATORY CONSULTANT

Consulting firm	Intertek Testing Services
Contact	JASON GOSS

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k100078/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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