

K082928 STRAIGHT FIRE HOLMIUM LASER FIBEROct 16, 2008
15 days to decisionK082928 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k082928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 1, 2008
Decision date	Oct 16, 2008
Days to decision	15 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	LAUREN B ANDERSON
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	KACHI C ENYINNA

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