FDA 510(k) Premarket Notification

CLEARED

K210925 Flexiva Pulse Laser Fiber, Flexiva Pulse Tractip Laser Fiber, Flexiva Pulse ID Laser Fiber, Flexiva Pulse ID TracTip Laser Fiber

Apr 28, 2021
30 days to decision

K210925 · Product code: **GEX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k210925/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 29, 2021
Decision date	Apr 28, 2021
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific**
Location	San Jose, CA, US
Contact	Rebecca Perrine
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. ...

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210925/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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