

K251759 Flexiva Pulse Laser FiberJul 9, 2025
30 days to decisionK251759 · Product code: **GEX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251759/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 9, 2025
Decision date	Jul 9, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Flexiva Pulse TracTip Laser Fiber; Flexiva Pulse ID Laser Fiber; Flexiva Pulse ID TracTip Laser Fibers

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Galit Gershon
Website	https://www.bostonscientific.com
510(k) history	229 submissions · 216 cleared · 2005-2026

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...