FDA 510(k) Premarket Notification

CLEARED

K252529 Moses™ 200 D/F/L Laser Fiber (M0068130100)

Oct 30, 2025
80 days to decision

K252529 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252529/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 11, 2025
Decision date	Oct 30, 2025
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Moses™ 365 D/F/L Laser Fiber (M0068130110); Moses™ 550 D/F/L Laser Fiber (M0068130120)

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Brandon Burris
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...