FDA 510(k) Premarket Notification

CLEARED

K200257 WallFlex Colonic Soft Stent System with Anchor Lock Delivery System, WallFlex Duodenal Soft Stent System with Anchor Lock Delivery System

Apr 17, 2020
74 days to decision

K200257 · Product code: **MQR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k200257/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Colonic, Metallic, Expandable (MQR)
Date received	Feb 3, 2020
Decision date	Apr 17, 2020
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Catherine Sanford
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...