FDA 510(k) Premarket Notification

CLEARED

K234046 WallFlex Colonic Stent System with Anchor Lock Delivery System

Mar 8, 2024
78 days to decision

K234046 · Product code: **MQR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k234046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stent, Colonic, Metallic, Expandable (MQR)
Date received	Dec 21, 2023
Decision date	Mar 8, 2024
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	WallFlex Duodenal Stent System with Anchor Lock Delivery System; WallFlex Colonic Soft Stent System with Anchor Lock Delivery System; WallFlex Duodenal Soft Stent System with Anchor Lock Delivery System

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Tijana Prodanovic
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...