

**K233939 Ultraflex Esophageal NG Stent System**Apr 29, 2024  
137 days to decisionK233939 · Product code: **ESW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k233939/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Dec 14, 2023
Decision date	Apr 29, 2024
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	WallFlex Esophageal Stent System

**APPLICANT**

---

Company	<b>Boston Scientific</b>
Location	San Jose, CA, US
Contact	Yanine Garcia-Quezada
Website	<a href="http://www.bostonscientific.com/">http://www.bostonscientific.com/</a>
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. ...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233939/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026