

**K091510 WALLFLEX ESOPHAGEAL FULLY COVERED STENT SYSTEM, MODELS M00516700, M00516710, M00516720, M00516730**Jun 26, 2009  
35 days to decisionK091510 · Product code: **ESW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k091510/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Esophageal (ESW)
Date received	May 22, 2009
Decision date	Jun 26, 2009
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Marybeth Gamber
Website	<a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a>
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...