

**K080332 POLYFLEX STENT SYSTEM WITH DELIVERY SYSTEM,  
MODEL M00514270, M00514280, 00514290, 00514300, 00514310,  
00514320, 00514330**Sep 5, 2008  
211 days to decisionK080332 · Product code: **ESW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k080332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Feb 7, 2008
Decision date	Sep 5, 2008
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	ASHLEY PYLE
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...