

**K083627 WALLFLEX BILIARY RX FULLY-COVERED STENT SYSTEM, MODEL M00570500,M00570510, M00570520, M00570530, M00570540**Apr 7, 2009  
120 days to decisionK083627 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k083627/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 8, 2008
Decision date	Apr 7, 2009
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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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...