

**K240464 WallFlex Biliary RX Stent System**Aug 30, 2024  
196 days to decisionK240464 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k240464/>**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	Feb 16, 2024
Decision date	Aug 30, 2024
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Epic Biliary Stent System; WallFlex Biliary RX Fully Covered Stent System RMV

**APPLICANT**

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Company	<b>Boston Scientific</b>
Location	San Jose, CA, US
Contact	Katherine Swanson
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. ...

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