

K140630 WALLFLEX BILIARY RX STENT SYSTEMMay 23, 2014
73 days to decisionK140630 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k140630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 11, 2014
Decision date	May 23, 2014
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	THOMAS HIRTE
Website	http://www.bostonscientific.com/
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.netDevice record: <https://www.510kdatabase.net/k140630/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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