

**K040027 BOSTON SCIENTIFIC EXPRESS BILIARY SD  
PREMOUNTED STENT SYSTEM**Mar 30, 2004  
82 days to decisionK040027 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k040027/>**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	Jan 8, 2004
Decision date	Mar 30, 2004
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific</b>
Location	San Jose, CA, US
Contact	CANDICE R BURNS
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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