CLEARED

K122072 WALLFLEXTM BILIARY RX STENT SYSTEM (UNCOVERED, PARTIALLY COVERED, AND FULLY COVERED) WALLFLEXTM BILIARY TRANSHEPATIC STE

Sep 28, 2012
74 days to decision

K122072 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k122072/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 16, 2012
Decision date	Sep 28, 2012
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	LAURIE PANNELLA
Website	https://www.bostonscientific.com
510(k) history	231 submissions · 218 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...