

K083374 WALLFLEX BILIARY RX PARTIALLY-COVERED STENT SYSTEMApr 22, 2009
160 days to decisionK083374 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k083374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 13, 2008
Decision date	Apr 22, 2009
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	Marybeth Gamber
Website	https://www.bostonscientific.com/
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...

CLINICAL EVIDENCE - NCT00713427**Study of the WallFlex™ Biliary Partially-covered Stent for the Palliative Treatment of Malignant Bile Duct Obstruction**

Status	Completed
Enrollment	70 patients (actual)
Study sites	6 sites
Condition studied	Biliary Strictures Caused by Malignant Neoplasms
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 1, 2008
Sponsor	Boston Scientific Corporation (Industry)

Primary outcome

Number of Participants With Absence of Recurrent Biliary Obstruction

Secondary outcome

Number of Adverse Events Related to the Device and/or Procedure

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT00713427

