FDA 510(k) Premarket Notification

K061231 WELLFLEX BILIARY RX STENT SYSTEM

CLEARED

Sep 1, 2006
122 days to decision

K061231 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k061231/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	May 2, 2006
Decision date	Sep 1, 2006
Days to decision	122 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	ALLYSON BARFORD
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k061231/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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