

K183636 SpyScope DS Access and Delivery Catheter, SpyScope DS II Access and Delivery Catheter, SpyGlass DS Digital Controller

Jan 22, 2019
27 days to decision

K183636 · Product code: **FBN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183636/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	Dec 26, 2018
Decision date	Jan 22, 2019
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Carter Navarro
Website	https://www.bostonscientific.com
510(k) history	229 submissions · 216 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...