

K181439 SpyGlass DS and DS II Direct Visualization SystemAug 23, 2018
83 days to decisionK181439 · Product code: **FBN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k181439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	Jun 1, 2018
Decision date	Aug 23, 2018
Days to decision	83 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...

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