

K191871 15F iSLEEVE Introducer Set, 14F iSLEEVE Introducer SetAug 7, 2019
26 days to decisionK191871 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k191871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 12, 2019
Decision date	Aug 7, 2019
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Kripa Pandya
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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Device record: <https://www.510kdatabase.net/k191871/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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