

K202478 Captivator Single-Use Polypectomy Snares, Captiflex Single-Use Polypectomy Snares

Oct 8, 2020
41 days to decisionK202478 · Product code: FDI · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k202478/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Snare, Flexible (FDI)
Date received	Aug 28, 2020
Decision date	Oct 8, 2020
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Stephanie Gorman
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/k202478/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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