

**K182169 AdVance XP Male Sling**Nov 27, 2018  
109 days to decisionK182169 · Product code: **OTM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k182169/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, For Stress Urinary Incontinence, Male (OTM)
Date received	Aug 10, 2018
Decision date	Nov 27, 2018
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Kaitlyn Rainbow
Website	<a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a>
510(k) history	231 submissions · 218 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...