

K172565 Advantage/Advantage Fit Delivery Device, Lynx Delivery Device, Obtryx Delivery Device (Curved & Halo), Obtryx II Delivery Device (Curved & Halo), Solyx SIS Delivery DeviceDec 20, 2017
117 days to decisionK172565 · Product code: **PWJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation, Surgical Mesh, Urogynecologic, Stress Urinary Incontinence (PWJ)
Date received	Aug 25, 2017
Decision date	Dec 20, 2017
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Anand Patel
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172565/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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