

**K122459 PINNACLE LITE PELVIC FLOOR REPAIR KIT,
POSTERIOR UPHOLD LITE VAGINAL SUPPORT SYSTEM**Dec 13, 2012
122 days to decisionK122459 · Product code: **OTP** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k122459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Aug 13, 2012
Decision date	Dec 13, 2012
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	MICHELLE BERRY
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/k122459/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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