FDA 510(k) Premarket Notification

K171271 Polyform Synthetic Mesh

CLEARED

Dec 15, 2017
228 days to decision

K171271 · Product code: **OTO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k171271/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed (OTO)
Date received	May 1, 2017
Decision date	Dec 15, 2017
Days to decision	228 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...