

K183619 Tactra Penile Prosthesis, 9.5 mm Device, Tactra Penile Prosthesis, 11 mm Device, Tactra Penile Prosthesis, 13 mm Device

Apr 16, 2019
111 days to decision

K183619 · Product code: **FAE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183619/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Dec 26, 2018
Decision date	Apr 16, 2019
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Laura Kelly
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...