FDA 510(k) Premarket Notification

K250824 Percuflex Ureteral Stent

CLEARED

Apr 15, 2025
28 days to decision

K250824 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250824/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stent, Ureteral (FAD)
Date received	Mar 18, 2025
Decision date	Apr 15, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Percuflex Plus Ureteral Stent; Percuflex Plus SureDrive Steerable Ureteral Stent Set; Contour Ureteral Stent; Contour SureDrive Steerable Ureteral Stent Set; Contour VL Variable Length Ureteral Stent; Contour VL SureDrive Steerable Ureteral Stent Set; Polaris Ultra Ureteral Stent; Polaris Loop Ureteral Stent; Tria Firm Ureteral Stent; Tria Soft Ureteral Stent; Percuflex Urinary Diversion Stent Set

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Stephanie Anderson
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...