FDA 510(k) Premarket Notification

CLEARED

K200260 Percuflex Ureteral Stent System, Percuflex Ureteral Stent System Kit, Percuflex Nephroureteral Stent System, Amplatz Anchor Catheter System

Apr 26, 2021
448 days to decision

K200260 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k200260/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Feb 3, 2020
Decision date	Apr 26, 2021
Days to decision	448 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Heidi Shearer
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...