CLEARED

Nov 10, 2022
506 days to decision

K211934 APDL Drainage Catheter System, Flexima APDL Drainage Catheter System, Flexima APDL Drainage Catheter System Kit with Dissolving Tip, Flexima APDL Drainage Catheter System with Dissolving Tip, Flexima APD Drainage Catheter System, Flexima APD Drainage Catheter System Kit, Flexima APD Drainage Catheter System with Dissolving Tip, Flexima APD Drainage Catheter System Kit with Dissolving Tip, Flexima Quickstick Drainage Catheter System, vanSonnenberg Drainage Cateter System, vanSonnenberg

K211934 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k211934/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Jun 22, 2021
Decision date	Nov 10, 2022
Days to decision	506 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Liz Johnston
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...