FDA 510(k) Premarket Notification

CLEARED

K902370 MODIFIED PROSTATIC URETHROPLASTY BALLOON CATHETER

Aug 17, 1990
80 days to decision

K902370 · Product code: **FAH** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k902370/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Urethral, Mechanical (FAH)
Date received	May 29, 1990
Decision date	Aug 17, 1990
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**Boston Scientific Corp**
Location	San Jose, CA, US
Contact	LEO L BASTA
Website	https://www.bostonscientific.com/
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...