

K953004 DILATATION CATHETER, BALLOONSep 13, 1995
77 days to decisionK953004 · Product code: **EZN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k953004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Jun 28, 1995
Decision date	Sep 13, 1995
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	Lorraine M Hanley
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...