

K903813 URETERAL BALLOON DILATATION CATHETERNov 7, 1990
79 days to decisionK903813 · Product code: **EZN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k903813/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dilator, Catheter, Ureteral (EZN) |
| Date received | Aug 20, 1990 |
| Decision date | Nov 7, 1990 |
| Days to decision | 79 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific Corp |
| Location | San Jose, CA, US |
| Contact | JEANNE M LESNIAK |
| 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...
