

**K953691 MS CLASSIQUE BALLOON CATHETER
W/HYDROPASS COATING**Oct 16, 1995
69 days to decisionK953691 · Product code: **EZN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k953691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Aug 8, 1995
Decision date	Oct 16, 1995
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Madox Medicals, Div. Boston Scientific Corp.
Location	Mchenry, IL, US
Contact	STEPHEN B ANDERSON
Website	https://www.bostonscientific.com
510(k) history	53 submissions · 47 cleared · 1976-1997

Madox Medicals, Div. Boston Scientific Corp. is a medical device manufacturer based in McHenry, US. Now part of Boston Scientific, the brand maintains a historical record of FDA 510(k) clearances. The company received FDA 510(k) clearances from total submissions between 1976 and 1997. Cardiovascular devices dominated the company's portfolio, representing 81% of all submissions. Notable cleared products include vascular grafts, balloon catheters, and cardiovascular patches used in surgical and interventional procedures. Madox Medicals is no longer active in FDA 510(k) su...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k953691/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 20, 2026