

**K953597 NOPROFILE OLBERT CATHETER SYSTEM BALLOON
DILATION CATHETER**Oct 7, 1995
67 days to decisionK953597 · Product code: **EZN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k953597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Aug 1, 1995
Decision date	Oct 7, 1995
Days to decision	67 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 Madox Medicals is no longer active in FDA 510(k) su...

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Device record: <https://www.510kdatabase.net/k953597/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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