

**K952887 NOPROFILE OLBERT CATHETER SYSTEM BALLOON
DILATATION CATHETER**Aug 18, 1995
56 days to decisionK952887 · Product code: **LJE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k952887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Jun 23, 1995
Decision date	Aug 18, 1995
Days to decision	56 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 Madox Medicals is no longer active in FDA 510(k) su...

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