

**K942635 MEADOX SURGIMED NOPROFILE OLBERT
CATHETER SYSTEM**Nov 1, 1994
151 days to decisionK942635 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k942635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jun 3, 1994
Decision date	Nov 1, 1994
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Meadox 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

Meadox 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. Meadox Medicals is no longer active in FDA 510(k) su...

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Device record: <https://www.510kdatabase.net/k942635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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