

**K953608 NOPROFILE OLBERT CATHETER SYSTEM BALLOON  
DILATATION CATHETER**Dec 20, 1995  
140 days to decisionK953608 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k953608/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 2, 1995
Decision date	Dec 20, 1995
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Madox Medicals, Div. Boston Scientific Corp.</b>
Location	Mchenry, IL, US
Contact	STEPHEN B ANDERSON
Website	<a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a>
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 Madox Medicals is no longer active in FDA 510(k) su...

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