

**K931386 HEMASHIELD MICROVEL/WOVEN DOUBLE VELOUR FABRIC**May 27, 1993  
70 days to decisionK931386 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k931386/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SP
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Mar 18, 1993
Decision date	May 27, 1993
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Madox Medicals, Div. Boston Scientific Corp.</b>
Location	Mchenry, IL, US
Contact	PATRICIA CHRISTIAN
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 Madox Medicals is no longer active in FDA 510(k) su...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k931386/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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