

**K955349 HEMASHIELD KNITTED DOUBLE VELOUR
CARDIOVASCULAR FABRIC**Feb 14, 1996
85 days to decisionK955349 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k955349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Nov 21, 1995
Decision date	Feb 14, 1996
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Meadox Medicals, Div. Boston Scientific Corp.
Location	Mchenry, IL, US
Contact	CAROLYN TAUBER
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 Meadox Medicals is no longer active in FDA 510(k) su...

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