

**K961847 HEMASHIELD VANTAGE (VASCULAR GRAFT)**Jan 22, 1997  
254 days to decisionK961847 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k961847/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	May 13, 1996
Decision date	Jan 22, 1997
Days to decision	254 days
Third-party review	No

**APPLICANT**

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 Madox Medicals is no longer active in FDA 510(k) su...