

**K811441 MANUFACTURING PROCESS CHANGE**Sep 16, 1981  
117 days to decisionK811441 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k811441/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	May 22, 1981
Decision date	Sep 16, 1981
Days to decision	117 days
Third-party review	No

**APPLICANT**

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Company	<b>Madox Medicals, Div. Boston Scientific Corp.</b>
Location	Mchenry, IL, US
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 Madox Medicals is no longer active in FDA 510(k) su...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/k811441/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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