FDA 510(k) Premarket Notification

K760516 FELT, SURGICAL DACRON

CLEARED

Jan 5, 1977
133 days to decision

K760516 · Product code: **DXZ** · Cardiovascular
Source: https://www.510kdatabase.net/k760516/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene (DXZ)
Date received	Aug 25, 1976
Decision date	Jan 5, 1977
Days to decision	133 days
Third-party review	No

APPLICANT

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 Meadox Medicals is no longer active in FDA 510(k) su...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k760516/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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