FDA 510(k) Premarket Notification

# K812248 COOLEY 2 VASCULAR PROSTHESIS STRAIGHT

**CLEARED**

Nov 24, 1981
105 days to decision

K812248 · Product code: **DSY** · Cardiovascular
Source: https://www.510kdatabase.net/k812248/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY) |
| Date received | Aug 11, 1981 |
| Decision date | Nov 24, 1981 |
| Days to decision | 105 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 Meadox Medicals is no longer active in FDA 510(k) su...

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Device record: https://www.510kdatabase.net/k812248/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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