FDA 510(k) Premarket Notification

K922674 NAVIGUIDE HYDROPHILIC COATED GUIDEWIRE

CLEARED

Dec 21, 1992
200 days to decision

K922674 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k922674/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 4, 1992
Decision date	Dec 21, 1992
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Meadox Medicals, Div. Boston Scientific Corp.**
Location	Mchenry, IL, US
Contact	NANCY C KOFFMAN
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 Meadox Medicals is no longer active in FDA 510(k) su...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/k922674/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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