

K943358 NAVIGUIDE HYDROPHILIC GUIDE WIREJun 2, 1995
325 days to decisionK943358 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k943358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 12, 1994
Decision date	Jun 2, 1995
Days to decision	325 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Madox Medicals, Div. Boston Scientific Corp.
Location	Mchenry, IL, US
Contact	STEPHEN B ANDERSON
Website	https://www.bostonscientific.com
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 Madox Medicals is no longer active in FDA 510(k) su...
