

K943522 THE PROMPT GUIDWIREDec 19, 1994
154 days to decisionK943522 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k943522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 18, 1994
Decision date	Dec 19, 1994
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Corp.
Location	McHenry, IL, US
Contact	MARLENE WRIGHT
Website	https://cordis.com
510(k) history	315 submissions · 281 cleared · 1976-2014

Cordis Corp. is a medical device manufacturer based in McHenry, US. The company specializes in interventional cardiovascular and gastroenterology devices. Cordis has a substantial FDA 510(k) regulatory history spanning from 1976 to 2014. The company received FDA 510(k) clearances from total submissions. Its portfolio focuses primarily on cardiovascular devices and gastroenterology stent systems, including percutaneous transluminal angioplasty catheters, emboli capture guidewires, and self-expanding biliary stent systems. Notable cleared products include the FLEXSTENT Bili...

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