

K904475 ENTREE SHEATH INTRODUCER SYSTEMApr 1, 1991
182 days to decisionK904475 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k904475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Oct 1, 1990
Decision date	Apr 1, 1991
Days to decision	182 days
Third-party review	No

APPLICANT

Company	Cordis Corp.
Location	Mchenry, IL, US
Contact	PEGGY R SINGER
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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