

K974448 CORDIS BRITE TIP CATHETER SHEATH INTRODUCER SYSTEMFeb 6, 1998
73 days to decisionK974448 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k974448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 25, 1997
Decision date	Feb 6, 1998
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Corp.
Location	Mchenry, IL, US
Contact	ARIEL MACTAVISH
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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