

**K983023 MODIFICATION TO CORDIS BRITE TIP CATHETER SHEATH INTRODUCER SYSTEM**Oct 1, 1998  
31 days to decisionK983023 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k983023/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 31, 1998
Decision date	Oct 1, 1998
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cordis Corp.</b>
Location	Mchenry, IL, US
Contact	ARIEL MACTAVISH
Website	<a href="https://cordis.com">https://cordis.com</a>
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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Device record: <https://www.510kdatabase.net/k983023/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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