

**K970392 CORDIS AVANTI+CATHETER SHEATH INTRODUCER SYSTEM**Apr 24, 1997  
80 days to decisionK970392 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k970392/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Feb 3, 1997
Decision date	Apr 24, 1997
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cordis Corp.</b>
Location	Mchenry, IL, US
Contact	ELENA S JUGO
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/k970392/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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