

K021593 MODIFICATION TO ENVOY AND VISTA BRITE TIPJun 13, 2002
29 days to decisionK021593 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k021593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	May 15, 2002
Decision date	Jun 13, 2002
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Corp.
Location	McHenry, IL, US
Contact	STEPHEN M ENOS
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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