

K112797 POWERFLEX PRO PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY CATHETERMay 4, 2012
221 days to decisionK112797 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k112797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Sep 26, 2011
Decision date	May 4, 2012
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Corp.
Location	Mchenry, IL, US
Contact	DANNA MARSHALL
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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