

**K971516 CORDIS POWERFLEX PLUS PTA BALLOON
CATHETER**Jul 23, 1997
86 days to decisionK971516 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k971516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 28, 1997
Decision date	Jul 23, 1997
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Corp.
Location	Mchenry, IL, US
Contact	MIRJAM BARBOZA
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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