

**K981407 OPTA LP PTA BALLOON CATHETER/POWERFLEX  
PLUS PTA BALLOON CATHETER**May 20, 1998  
30 days to decisionK981407 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k981407/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 20, 1998
Decision date	May 20, 1998
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cordis Corp.</b>
Location	Mchenry, IL, US
Contact	MIRJAM BARBOZA
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/k981407/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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