

**K942094 CORDIS SAVVY PTA BALLOON CATHETER**Nov 1, 1994  
183 days to decisionK942094 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k942094/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 2, 1994
Decision date	Nov 1, 1994
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cordis Corp.</b>
Location	Mchenry, IL, US
Contact	COLLEEN HAHNEN
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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