

**K050645 CORDIS AMIIA .014 PTA BALLOON CATHETER**Apr 1, 2005  
18 days to decisionK050645 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k050645/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                    |
| Submission type       | Special   |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received         | Mar 14, 2005  |
| Decision date         | Apr 1, 2005   |
| Days to decision      | 18 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cordis Corp.</b>                                 |
| Location       | Mchenry, IL, US                                     |
| Contact        | KAREN WILK  |
| 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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