

K946052 POWERFLEX(TM) 5F PTA BALLOON CATHETERMar 3, 1995
81 days to decisionK946052 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k946052/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Dec 12, 1994 |
| Decision date | Mar 3, 1995 |
| Days to decision | 81 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Cordis Corp. |
| Location | Mchenry, IL, US |
| Contact | MARLENE W VALENTI |
| 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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