

**K991673 CORDIS TEMPO ANGIOGRAPHY CATHETER**May 26, 1999  
9 days to decisionK991673 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k991673/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Special                                   |
| Device classification | Catheter, Intravascular, Diagnostic (DQO) |
| Date received         | May 17, 1999                              |
| Decision date         | May 26, 1999                              |
| Days to decision      | 9 days                                    |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cordis Corp.</b>                                 |
| Location       | McHenry, IL, US                                     |
| Contact        | ARIEL MACTAVISH                                     |
| 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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