

**K780885 CORDIA R**Jan 17, 1979  
236 days to decisionK780885 · Product code: **GOL** · Microbiology  
Source: <https://www.510kdatabase.net/k780885/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Antigen, Ha (including Ha Control), Rubella (GOL) |
| Date received         | May 26, 1978                                      |
| Decision date         | Jan 17, 1979                                      |
| Days to decision      | 236 days  |
| Third-party review    | No  |

**APPLICANT**

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