

**K781058 C-DAK 4000 ARTIFICIAL KIDNEY**Aug 23, 1978  
61 days to decisionK781058 · Product code: **FJI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k781058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Jun 23, 1978
Decision date	Aug 23, 1978
Days to decision	61 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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