

**K801354 BIONICS ARTERIAL/VENOUS FISTULA NEEDLE**Jul 8, 1980  
29 days to decisionK801354 · Product code: **KOC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k801354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Jun 9, 1980
Decision date	Jul 8, 1980
Days to decision	29 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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