

K782021 A.V. FISTULA NEEDLE SETMar 21, 1979
106 days to decisionK782021 · Product code: **FIE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k782021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Dec 5, 1978
Decision date	Mar 21, 1979
Days to decision	106 days
Third-party review	No

APPLICANT

Company	Cordis Corp.
Location	Mchenry, IL, US
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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