

K812540 CORDIA IMSep 24, 1981
20 days to decisionK812540 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k812540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Sep 4, 1981
Decision date	Sep 24, 1981
Days to decision	20 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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