FDA 510(k) Premarket Notification

K800704 C-DAK TM 2800 ARTIFICIAL KIDNEY

CLEARED

May 8, 1980
38 days to decision

K800704 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k800704/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Mar 31, 1980
Decision date	May 8, 1980
Days to decision	38 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k800704/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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