FDA 510(k) Premarket Notification

K802613 C-PAK MODEL 12 ARTIFICIAL KIDNEY

CLEARED

Jan 7, 1981
78 days to decision

K802613 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k802613/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Oct 21, 1980
Decision date	Jan 7, 1981
Days to decision	78 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...