FDA 510(k) Premarket Notification

K851913 CORDIS HIGH-TORQUE TEMP. PERVENOUS LEAD W/DEPTH MA

CLEARED

Sep 16, 1985
138 days to decision

K851913 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k851913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	May 1, 1985
Decision date	Sep 16, 1985
Days to decision	138 days
Third-party review	No

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	BETTY HERNANCEL
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...