FDA 510(k) Premarket Notification

K862244 MODIFICATIONS TO CORDIS' SUPER FLOW CATHETERS

CLEARED

Aug 25, 1986
74 days to decision

K862244 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k862244/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jun 12, 1986
Decision date	Aug 25, 1986
Days to decision	74 days
Third-party review	No

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	DONNA L ROGERS
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...