FDA 510(k) Premarket Notification

K001135 6F & 7F INTRODUCING CATHETERS (MODIFICATION)

CLEARED

Jul 3, 2000
84 days to decision

K001135 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k001135/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Apr 10, 2000
Decision date	Jul 3, 2000
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	DENNIS S GRIFFIN
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...