FDA 510(k) Premarket Notification

K003920 CORDIS M3 PTA DILATATION CATHETER

CLEARED

Jun 15, 2001
178 days to decision

K003920 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k003920/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 19, 2000
Decision date	Jun 15, 2001
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	CHARLES (CHUCK) J RYAN
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...