FDA 510(k) Premarket Notification

K915498 CORDIS ANGIOGRAPHIC DOPPLER CATHER

CLEARED

Apr 17, 1992
130 days to decision

K915498 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k915498/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Dec 9, 1991
Decision date	Apr 17, 1992
Days to decision	130 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	MIRJAM BARBOZA
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...