FDA 510(k) Premarket Notification

CLEARED

K010083 TRAPEASE PERMANENT VENA CAVA FILTER AND INTRODUCTION KIT, MODEL 466-P306A

Jun 6, 2001
146 days to decision

K010083 · Product code: **DTK** · Cardiovascular
Source: https://www.510kdatabase.net/k010083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	Jan 11, 2001
Decision date	Jun 6, 2001
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	KAREN WILK
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...