FDA 510(k) Premarket Notification

CLEARED

K042969 MODIFICATION TO SMART CONTROL NITINOL STENT TRANSHEPATIC BILIARY SYSTEM

Nov 8, 2004
11 days to decision

K042969 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k042969/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 28, 2004
Decision date	Nov 8, 2004
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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