

K010411 PALMAZ GENESIS TRANSHEPATIC BILIARY STENT AND DELIVERY SYSTEMAug 27, 2001
196 days to decisionK010411 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k010411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Abbreviated
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 12, 2001
Decision date	Aug 27, 2001
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Corp.
Location	Mchenry, IL, US
Contact	CHARLES 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...

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