FDA 510(k) Premarket Notification

CLEARED

K033394 CORDIS PALMAZ GENESIS TRANSHEPATIC BILLARY STENT ON OPTA PRO .035 DELIVERY SYSTEM

Dec 22, 2003
60 days to decision

K033394 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k033394/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 23, 2003
Decision date	Dec 22, 2003
Days to decision	60 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k033394/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 28, 2026