

K972825 OPTA5 PTA BALLOON CATHETER, POWERFLEX PTA BALLOON CATHETER, ULTRA-THIN DIAMOND BALLOON CATHETER, PALMAZ BALLOON EXPANDABOct 7, 1997
90 days to decisionK972825 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k972825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 9, 1997
Decision date	Oct 7, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

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...