

K130981 FLEXSTENT BILIARY SELF EXPANDING STENT SYSTEMMar 12, 2014
337 days to decisionK130981 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k130981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 9, 2013
Decision date	Mar 12, 2014
Days to decision	337 days
Third-party review	No
Summary / Statement	Statement
Other names	S.M.A.R.T. RE-FLEX BILIARY ELF-EXPANDING STENT SYSTEM

APPLICANT

Company	Cordis Corp.
Location	Mchenry, IL, US
Contact	KIM FONDA
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...