

**K023217 MODIFICATION TO SMART CONTROL NITINOL STENT  
TRANSHEPATIC BILIARY SYSTEM**Oct 25, 2002  
29 days to decisionK023217 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k023217/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Sep 26, 2002
Decision date	Oct 25, 2002
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cordis Corp.</b>
Location	Mchenry, IL, US
Contact	SAM MIRZA
Website	<a href="https://cordis.com">https://cordis.com</a>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k023217/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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