

**K051785 FORMULA 418 BILIARY STENT**Aug 23, 2005  
53 days to decisionK051785 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k051785/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 1, 2005
Decision date	Aug 23, 2005
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook, Inc.</b>
Location	Mchenry, IL, US
Contact	KAREN BRADBURN
510(k) history	190 submissions · 179 cleared · 1976-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051785/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026