

K052539 COOK FORMULA 418 BILIARY STENT SYSTEMDec 9, 2005
85 days to decisionK052539 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k052539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Sep 15, 2005
Decision date	Dec 9, 2005
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052539/> 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 14, 2026