

**K010601 FANELLI BILIARY STENT**Nov 16, 2001  
261 days to decisionK010601 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k010601/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 28, 2001
Decision date	Nov 16, 2001
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook, Inc.</b>
Location	Mchenry, IL, US
Contact	LISA HOPKINS
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/k010601/> 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