

**K040505 ZILVER 635 BILIARY STENT**Mar 16, 2004  
18 days to decisionK040505 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k040505/>**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	Feb 27, 2004
Decision date	Mar 16, 2004
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook, Inc.</b>
Location	Mchenry, IL, US
Contact	LELAND KEYT
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/k040505/> 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