

K043481 MODIFICATION TO: ZILVER 635 BILIARY STENTDec 29, 2004
14 days to decisionK043481 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k043481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 15, 2004
Decision date	Dec 29, 2004
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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