

K080037 MODIFICATION TO ZILVER 635 BILIARY STENTAug 1, 2008
207 days to decisionK080037 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k080037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jan 7, 2008
Decision date	Aug 1, 2008
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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