

K121430 EVOLUTION BILIARY STENT SYSTEMMar 1, 2013
291 days to decisionK121430 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k121430/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	May 14, 2012
Decision date	Mar 1, 2013
Days to decision	291 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Ireland, Ltd.
Location	Limerick, IE
Contact	Jacinta Kilmartin
510(k) history	32 submissions · 27 cleared · 2005-2024

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