

K163018 Zilver 635 Biliary StentDec 23, 2016
53 days to decisionK163018 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k163018/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 31, 2016
Decision date	Dec 23, 2016
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Ireland, Ltd.
Location	Limerick, IE
Contact	Nora O'Connor
510(k) history	32 submissions · 27 cleared · 2005-2024

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