

K182980 Zilver 518 Biliary Stent, Zilver 635 Biliary StentNov 16, 2018
18 days to decisionK182980 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 29, 2018
Decision date	Nov 16, 2018
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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