

K163169 Zilver 518TM Biliary StentFeb 7, 2017
85 days to decisionK163169 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k163169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 14, 2016
Decision date	Feb 7, 2017
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary
Other names	Zilver 635TM Biliary Stent

APPLICANT

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

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