

K213946 Compass BDS Biliary StentMay 9, 2022
143 days to decisionK213946 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 17, 2021
Decision date	May 9, 2022
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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