

K172057 Zimmon Pancreatic Stents/Stent sets, Geenen Pancreatic Stents/Stent Sets, Pushing Catheter and Guiding Catheter, Johlin Pancreatic Wedge Stent and Introducer Set

Mar 9, 2018
246 days to decision

K172057 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172057/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 6, 2017
Decision date	Mar 9, 2018
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k172057/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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