

K233079 Zimmon® Pancreatic Stents/Stent sets (SPSOF, SPSOS, ZEPDF, ZEPDS, ZPSOF, ZPSOS)

Jun 14, 2024
262 days to decision

K233079 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233079/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Sep 26, 2023
Decision date	Jun 14, 2024
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Geenen® Pancreatic Stents/Stent Sets (GEPD, GPDS, GPSO, GPSOS); Johlin® Pancreatic Wedge Stent and Introducer Set (JPWS); Pushing Catheter and Guiding Catheter (GC, PC); Geenen® Sof-Flex® Pancreatic Stent (GPSO-SF. GPSOS-SF)

APPLICANT

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