

**K171623 Nasal Pancreatic Drainage Set**Jul 31, 2017  
59 days to decisionK171623 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k171623/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 2, 2017
Decision date	Jul 31, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171623/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026