

**K222627 EndoGI S-Path Biliary Stent System**Sep 28, 2022  
28 days to decisionK222627 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k222627/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 31, 2022
Decision date	Sep 28, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endo GI Medical</b>
Location	Nazareth, IL
Contact	Omri Naveh
510(k) history	2 submissions · 2 cleared · 2020-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedoss, Inc.</b>
Contact	Bosmat Friedman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222627/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026