

K202477 EndoGI S-Path Biliary Stent SystemSep 24, 2020
27 days to decisionK202477 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k202477/>**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 28, 2020 |
| Decision date | Sep 24, 2020 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202477/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026