FDA 510(k) Premarket Notification

K222627 EndoGI S-Path Biliary Stent System

CLEARED

Sep 28, 2022
28 days to decision

K222627 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k222627/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**ProMedoss, Inc.**
Contact	Bosmat Friedman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov