FDA 510(k) Premarket Notification

K232596 EndoGI S-Path Biliary Stent System

CLEARED

Sep 27, 2023
33 days to decision

K232596 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232596/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 25, 2023
Decision date	Sep 27, 2023
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Endogi Medical, Ltd.**
Location	Nazareth, IL
Contact	Omri Naveh
510(k) history	2 submissions · 1 cleared · 2020-2023

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

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Device record: https://www.510kdatabase.net/k232596/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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