September 28, 2022

EndoGI Medical
% Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, NC 28269

Re: K222627
Trade/Device Name: EndoGI S-Path Biliary Stent System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: August 31, 2022
Received: August 31, 2022

Dear Bosmat Friedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any

Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

April Marrone, Ph.D., MBA
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222627

Device Name
EndoGI S-Path Biliary Stent System

Indications for Use *(Describe)*
The EndoGI S-Path Biliary Stent System is intended for delivery of stent(s) to the biliary tract for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY [SPECIAL 510(K)]
EndoGI S-Path Biliary Stent System
510(k) Number K222627

1. SUBMITTER

Applicant's Name:
EndoGI Medical
Omri Naveh, CEO
13 Wadi El Haj
P.O. Box 1252
Nazareth, Israel
+972-52-462-5474
+972-4-609-8600
omri@EndoGI-Medical.com

Primary Contact:
Bosmat Friedman
Regulatory Affairs Consultant
3521 Hatwynn Rd.
Charlotte, NC 28269
Phone: 647-975-3974
bosmat.f@promedoss.com

Date Prepared: August 31, 2022

2. DEVICE

Trade Name:
EndoGI S-Path Biliary Stent System

Classification: **Name:** Biliary catheter and accessories
Product Code: FGE
Regulation No: 876.5010
Class: 2
Review Panel: Gastroenterology/Urology

3. PREDICATE DEVICES

Predicate device: EndoGI Biliary Stent System, by EndoGI Medical, Ltd., Product code FGE, cleared Under: K202477.

4. DEVICE DESCRIPTION

The EndoGI S-Path Biliary Stent System consists of a stent and stent delivery catheter. The EndoGI S-Path Biliary Stent System catheter is 10 Fr in diameter and includes a single preloaded stent available in three lengths (80, 110 and 140 mm). The delivery catheter is compatible with a guidewire of up to 0.035". EndoGI S-Path Biliary System stents have a

straight body and one end incorporating a 65° bend (duodenal bend). Stents are comprised of a biocompatible radiopaque plastic which allows visualization of the stent post deployment.

5. INDICATIONS FOR USE

The EndoGI S-Path Biliary Stent System is intended for delivery of stent(s) to the biliary tract for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone.

6. SUBSTANTIAL EQUIVALENCE

The EndoGI S-Path System is substantially equivalent to the predicate device based on the following:

Intended Use
The intended use of the proposed device is identical to that of the cleared device.

Technology
The revised system incorporates two new stent sizes, 80 mm and 140 mm. As a result, the overall system length was extended, and minor improvements were also incorporated in the delivery system. Repeat bench testing demonstrated that the system functions as intended and yielded substantially equivalent results to the results obtained with the predicate.

Discussion
The EndoGI S-Path System has identical indications for use as the previously cleared EndoGI System. The main technological difference between the EndoGI S-Path delivery system and the predicates is due to the addition of two stent sizes. This modification resulted in a longer delivery system. Repeat performance testing demonstrated that both systems function in an equivalent manner.

7. PERFORMANCE DATA

Validation Testing
Due to the modifications to the EndoGI S-Path; mechanical, dimensional, kink resistance and flow rate testing were repeated to demonstrate the system functions as intended. The results of the validation testing demonstrated that the EndoGI S-Path system is as safe and effective as its predicate and that the modifications to the system did not raise new questions of safety and effectiveness.

8. CONCLUSION

EndoGI Medical has demonstrated that the EndoGI S-Path System is substantially equivalent to the predicate device. Differences between the proposed S-Path System and the predicate device do not raise new questions of safety or efficacy.