September 24, 2020

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

Re: K202477
Trade/Device Name: EndoGI S-Path Biliary Stent System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: August 27, 2020
Received: August 28, 2020

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,

for
Glenn B. Bell, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202477

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 K202477

I. SUBMITTER

Applicant's Name:
EndoGI Medical
Omri Naveh, CEO
4625474-52-972+
6098600-4-972+
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

II. DEVICE

Trade Name:
EndoGI S-Path Biliary Stent System

Classification Code:
Name: Catheter, Biliary, Diagnostic
Product Code: FGE
Regulation No: 876.5010
Class: 2
Review Panel: Gastroenterology/Urology

III. PREDICATE DEVICES

Predicate device EndoGI Biliary Stent System, by EndoGI Medical, Ltd., Product code FGE, cleared Under: K193600.

IV. DEVICE DESCRIPTION

The revised EndoGI S-Path System incorporates one preloaded stent which has a straight body and one end incorporating a 65º bend (duodenal bend). The stent is identical to the previously cleared EndoGI stent and is comprised of a biocompatible radiopaque plastic which allows visualization of the stent post deployment.

The EndoGI S-Path System is available 10 Fr and includes a single preloaded 110 mm stent. The system is compatible with a guidewire of up to 0.035".

V. 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.

VI. 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 a single stent rather than the two preloaded stents available on the predicted. As a result, the overall system length was shortened, and the handle design simplified. Repeat bench testing demonstrated that the system functions as intended and yielded substantially equivalent results to the results obtained with the predicate. Since the previously cleared system represents a "worst-case-scenario" with respect to shelf life, sterilization and biocompatibility testing, these tests were not repeated as they are fully applicable to the EndoGI S-Path System.

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 elimination of one stent from the original double stent system. This modification resulted in a shorter delivery system with a simplified handle. Repeat performance testing demonstrated that both system function in an equivalent manner. Consequently, it is clear that the EndoGI S-Path System is as safe and effective as its predicate without raising any new safety and/or effectiveness concerns.

VII. PERFORMANCE DATA

Validation Testing
Due to the modifications to the delivery system mechanical and kink resistance 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.
Since no modifications were made to the system materials, packaging or manufacturing processes, there was no need to repeat biocompatibility, sterilization or shelf-life testing.

VIII. 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.