September 27, 2023

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

Re: K232596
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 25, 2023
Received: August 25, 2023

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 (the 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 and the limitations described below. 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 available 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.

The OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system has not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Kellie B. Kelm -S

for
Courtney H. Lias, Ph.D.
Director
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.

Submission Number *(if known)*

K232596

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.

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510(K) SUMMARY [SPECIAL 510(K)]
EndoGI S-Path Biliary Stent System
510(k) Number K232596

1. SUBMITTER

Applicant's Name:
EndoGI Medical
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Date Prepared: August 23, 2023

2. 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

3. PREDICATE DEVICES

Predicate device EndoGI Biliary Stent System, by EndoGI Medical, Ltd., Product code FGE, cleared Under: K222627, K202477 and K193600.

4. 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 stent available in three lengths (80, 110 and 140 mm). The system is compatible with a guidewire of up to 0.035".

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 stent component of the EndoGI S-Path system is identical to the previously cleared EndoGI S-Path system. No changes were made to this component and therefore it is substantially equivalent to the previously cleared stent under K222627.
While some minor modifications were made to lengths of the system, the handle and the Inner material, the mechanism of action remains unchanged. Comparative testing as well as biocompatibility tests and sterilization validation were provided in support of the proposed modifications.

Discussion
The EndoGI S-Path System has identical indications for use as the previously cleared EndoGI System. The minor modifications to the delivery system were evaluated ia comparative testing demonstrating the devices 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.

7. PERFORMANCE DATA

Due to the modifications to the delivery system mechanical performance, dimensional testing and kink were repeated to demonstrate the system functions as intended. Additionally, biocompatibility tests of the delivery device and sterilization validation were also cobducted to support the proposed modifications. 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.