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

Re: K193600
Trade/Device Name: EndoGI Biliary Stent System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: May 27, 2020
Received: May 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,

Daniel G. Walter, Jr.
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
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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)*
K193600

Device Name
EndoGI Biliary Stent System

Indications for Use *(Describe)*
The EndoGI 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.

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1 SUBMITTER

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Date Prepared:
December 20, 2019

2 DEVICE

Trade Name:
EndoGI Biliary Stent System

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

3 PREDICATE DEVICE

Primary predicate device:

- AdvaniX™ Biliary Stent with NaviFleX™ RX Delivery System, manufactured by Boston Scientific, cleared under K101314; Product Code: FGE.

Reference device:

- Marathon Stent with Fusion Technology, manufactured by Cook Ireland, cleared under K060624; Product code: FGE.

4 DEVICE DESCRIPTION

The EndoGI System incorporates two preloaded stents. Both stents are identical in design with a straight body and one end incorporating a 65º bend (duodenal bend). The stents are comprised of a biocompatible radiopaque plastic which allows visualization of the stents post deployment. Both stents are pre-mounted on the delivery system and are delivered via near-the-wire and over-the-wire methods.

The EndoGI System is available 10 Fr and includes two 110 mm stents. The system is compatible with a guidewire of up to 0.035". The safety lock mechanisms are incorporated within the delivery device handle.

5 INDICATIONS FOR USE

The EndoGI 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 Biliary Stent System is substantially equivalent to the Advanix™ Biliary Stent with NaviFlex™ RX Delivery System. Both devices have similar indications for use; the main difference is that the EndoGI System allows the insertion of two stents on one delivery device while the predicate requires two separate delivery device insertions in order to achieve the same results.
Bothe devices incorporate a combination of rapid exchange and over-the-wire techniques to deliver the stent(s). Comparative bench testing demonstrated that the stent components of both systems are substantially equivalent. Additional bench and animal testing on the EndoGI delivery device demonstrated that the device performs as intended and that no new safety and effectiveness concerns have been introduced due to the ability of the system to deliver two stents.

Feature	EndoGI System	Advanix™ (K101314)	Comparison to Primary Predicate
Reg. Number	876.5010	876.5010	Same
Product Code	FGE	FGE	Same
Indication for Use	The EndoGI 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.	Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is intended for delivery of the stent 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.	Similar-with the addition of the ability to place two stents with one passage over the guide wire
Principle of Operation	Combination of rapid exchange and over-the-wire techniques to deliver and place two stents	Combination of rapid exchange and over-the-wire techniques to deliver a single stent	Similar; The performance of the EndoGI System was evaluated via bench and animal testing, the results of which support our substantial equivalency claim

Feature	EndoGI System	Advanix™ (K101314)	Comparison to Primary Predicate
Material	Various polymers and stainless steel	Various polymers and stainless steel	Similar; delivery system and stent successfully passed all biocompatibility testing
Single use	Yes	Yes	Same
Sterility	EtO	EtO	Same
Mechanical Properties			
Tensile test	Obtained results supports substantial equivalency claim		Similar
Compression test	Obtained results supports substantial equivalency claim		Similar
Flow Rate	Obtained results supports substantial equivalency claim		Similar

7 PERFORMANCE DATA

Biocompatibility:

The following biocompatibility tests were performed on the stent and delivery system:

Stent:

- Systemic Toxicity (Implant Method) and Implant Evaluation Test in Rabbits
- Systemic Toxicity (Dual Route Repeated Exposure Method) Test
- Material Mediated Pyrogenicity Test (ISO/USP)
- Acute Systemic Toxicity Test
- Guinea Pig Maximization Test
- lntracutaneous Reactivity Test
- Mouse Lymphoma Assay
- Ames Bacterial Reverse Mutation Assay
- MEM Elution Cytotoxicity Assay

Delivery System:

For the delivery device:

- MEM Elution Cytotoxicity Assay
- Material Mediated Pyrogenicity Test
- Acute Systemic Toxicity Test
- Guinea Pig Maximization Test
- Intracutaneous Reactivity Test

Non-Clinical Performance Testing:

The EndoGI Biliary Stent System device has undergone and successfully passed the following tests:

- Mechanical Evaluation
- Kink Resistance
- Flow Rate
- Bond Strength
- Dimensional Verification

- EndoGI Biliary Stent Compression Force (Bile)
- EndoGI Biliary Stent Tensile Test (Bile)

Animal Performance Testing:

A GLP-like animal study on porcine model was conducted to evaluate the performance of the system and to validate its ability to successfully deploy two stents.
A total of 6 repeats including 2 deployments and 6 stent retrievals were performed. The duration of the complete procedure (from delivery system insertion to the beginning of monitoring following retrieval) was 17 minutes – 29 minutes with an average of 20 minutes per repeat. The second stent deployment following the first stent was performed within 1-2 minutes with an average of 1 minute for second stent deployment.
The goals of the study were met; namely, the system was able to successfully deliver 2 stents utilizing a one-step procedure, no local tissue reaction was visualized, and successful stent removal was achieved.

8 CONCLUSION

The EndoGI System has similar indications for use as the main predicate, the Advanix™ Biliary Stent with NaviFlex™ RX Delivery System. Although the indications for use statement of the Advanix addresses the placement of only one stent, the product labeling clearly demonstrates that multiple stent placement with the Advanix is actively promoted. Furthermore, multiple stent placement is common practice and therefore the ability of the EndoGI System to allow for the placement of two stents does not raise new safety or effectiveness concerns. The main technological difference between the EndoGI delivery system and the predicates is due to the systems' ability to incorporate two preloaded stents in one system. We believe that no new safety and effectiveness concerns are raised due to this technological difference. With respect to mode of operation, the EndoGI System utilizes a combination of rapid exchange and over-the-wire techniques to deliver the stents to the desired location, this is identical to the mode of operation of the identified predicates. The company has provided sufficient comparative testing between the EndoGI System and Advanix predicate as well as additional pre-clinical bench and animal data to demonstrate our substantial equivalency claim. Consequently, it is clear that the EndoGI System is as safe and effective as its primary predicate without raising any new safety and/or effectiveness concerns.