March 3, 2023

Endolumik, Inc.
% Michael Nilo
President
Nilo Medical Consulting Group
3491 Denny Street
Pisstburgh, PA 15201

Re: K222880
Trade/Device Name: Endolumik Fluorescence Guided Gastric Calibration Tube (FG Bougie)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: February 1, 2023
Received: February 1, 2023

Dear Michael Nilo:

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,

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Je Hi An, Ph.D.
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)*
K222880

Device Name
Endolumik Fluorescence Guided Gastric Calibration Tube (FG Bougie)

Indications for Use *(Describe)*
The Endolumik Fluorescence Guided Gastric Calibration Tube (FG Bougie) is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation, to test for leaks, to provide visualization of the tube position, and to serve as a sizing and measurement guide.

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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This 510(k) Summary was prepared in accordance with 21 CFR 807.92

1. Date Prepared

1 March 2023

2. Submitter

Applicant: Endolumik, Inc
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3. Device Information

Trade Name: Endolumik Fluorescence Guided Gastric Calibration Tube (FG Bougie)

Common Name: Gastrointestinal tube and accessories

Device Classification: Tubes, Gastrointestinal (and Accessories)
Regulation: 21 CFR 876.5980
Product Code: KNT
Class: II

4. Predicate Device Information

Trade Name: Visigi 3D

510(k) Number: K130483

Common Name: Gastrointestinal tube and accessories

Device Classification: Tube, Gastrointestinal (and Accessories)
Regulation: 21 CFR 876.5980
Product Code: KNT
Class: II

5. Device Description

The Endolumik Fluorescence Guided Gastric Calibration Tube is a flexible gastric tube for use in gastric and bariatric surgery. It may be used for the following: the application of suction, stomach decompression, drainage of gastric fluids, irrigation, to test for leaks, to provide visualization of the tube position, and to serve as a sizing and measurement guide.

The Endolumik Gastric Calibration Tube is a non-sterile, single patient use device. The tube is 80 cm long and is available in 2 different diameters: 36 and 40 French. It has a rounded tip and small side holes at the distal end. The proximal end includes a handle with an integral suction regulator. An additional squeeze bulb with pressure gauge may be attached to the end of the regulator.

6. Indications for Use

The Endolumik Fluorescence Guided Gastric Calibration Tube (FG Bougie) is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation, to test for leaks, to provide visualization of the tube position, and to serve as a sizing and measurement guide.

7. Technological Comparison

The Endolumik Gastric Calibration Tube is similar to the predicate with minor differences in length and material of the tube.

The minor differences in design do not raise new questions of safety or effectiveness. Endolumik has evaluated these characteristics using bench test methods.

8. Comparison of Technical Characteristics with the Predicate Device

Table 1: Comparison of the Endolumik to the predicate device

	Endolumik	**Predicate Visigi 3d (K130483)**	**Comparison**
Class	II	II	Same
Product Code	KNT	KNT	Same
Regulation	876.5980	876.5980	Same
Indication for Use Statement	The Endolumik Gastric Calibration Tube is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation, to test for leaks, to provide visualization of the tube position, and to serve as a sizing guide.	The Boehringer Laboratories Gastric Sizing Tube is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation, and to serve as a sizing guide.	Similar
Typical Use	Gastric and bariatric procedures	Gastric and bariatric procedures	Same
Environments of Use	Surgery centers, hospitals	Surgery centers, hospitals	Same
Patient Population	Individuals undergoing bariatric and/or gastric procedures	Individuals undergoing bariatric and/or gastric procedures	Same
Intraoperative Use	Yes	Yes	Same
Functions	Suction, drainage, sizing, irrigation.	Suction, drainage, sizing, irrigation.	Same
Outer Diameter/ French Size	36F, 40F	32F, 36F, 40F	Same
Length	92cm	76cm	Similar

Tubing	Multi lumen with rounded, closed distal end	Single lumen with rounded, closed distal end	Different design Established equivalence via testing
Distal Side Holes/ Decompression Capability	Yes	Yes	Same
Connector for Suction	Yes	Yes	Same
Slide Valve	No	Yes	Different design Established equivalence via testing
Tubing material	PVC	Styrene-Ethylene-Butylene-Styrene (SEBS co-polymer)	Different design Established equivalence via testing
Markings	Markings every 5mm on distal end; Markings every 10cm on proximal end	No markings	Different Established equivalence via justification
Sterility	Supplied non-sterile, disposable, single patient use.	Supplied non-sterile, disposable, single patient use.	Same
LED Guide Lights	Yes	No	Different design Established equivalence via testing
LED wavelength	697-766nm	n/a	Different Established equivalence via testing

9. Non-clinical and/or Clinical Test Summary and Conclusions

Test Summary

The following testing was conducted to support substantial equivalence:

- Cytotoxicity Test, MEM/Agar Overlay/Direct Contact per ISO 10993-5
- Skin Sensitization Study, Magnusson-Kligman Polar and Non-polar Extraction per ISO 10993-10
- Acute Irritation/Intracutaneous Reactivity, Polar and Non-polar Extraction per ISO 10993-10
- EMC Evaluation per IEC 60601-1-2 and 60601-2-18
- Electrical Safety Evaluation per IEC 60601-1
- Light Safety Evaluation per IEC 62471
- Packaging Integrity per ASTM D4169
- Dimensional Analysis
- Tip Connection to Tube Joint Strength Test
- Fixed Deflection Testing
- Torsion Testing
- Buckling Testing
- Kink Testing
- Drainage Testing
- Irrigation Testing
- Suction Testing
- Leak Testing
- Bulb Compatibility

The biocompatibility, EMC, electrical safety, and performance testing demonstrate substantial equivalence to the predicate device.

10. Conclusion

In conclusion, the proposed FG Bougie has the same classification information, the same intended use, and similar technologies as the predicate device. According to performance tests conducted, the device is as safe, as effective, and performs as well as the predicate device.