February 8, 2024

Endolumik
% Michael Nilo
President
Nilo Medical Consulting Group
3706 Butler Street, #313
Pittsburgh, Pennsylvania 15201

Re: K240069
Trade/Device Name: Endolumik Gastric Calibration Tube M Series (EGCT36M); Endolumik Gastric Calibration Tube M Series (EGCT40M)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT, FAT
Dated: January 8, 2024
Received: January 9, 2024

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 (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. 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.

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,

Anthony Lee -S

Anthony C. Lee, 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)*
K240069

Device Name
Endolumik Gastric Calibration Tube M Series (EGCT36M); Endolumik Gastric Calibration Tube M Series (EGCT40M)

Indications for Use *(Describe)*
The EndolumikGastric 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 tube is also indicated for use in esophageal surgical procedures as an esophageal bougie and to provide visualization of the tube position.

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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510(k) Summary

Prepared on: 2024-01-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ENDOLUMIK
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Applicant Contact	Mrs. Mara McFadden
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Correspondent Name	Nilo Medical Consulting Group
Correspondent Address	3706 Butler Street, #313 Pittsburgh PA 15201 United States
Correspondent Contact Telephone	717.421.4396
Correspondent Contact	Mr. Michael Nilo
Correspondent Contact Email	michael.nilo@nilomedicalconsulting.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Endolumik Gastric Calibration Tube M Series (EGCT36M); Endolumik Gastric Calibration Tube M Series (EGCT40M)
Common Name	Gastrointestinal tube and accessories
Classification Name	Tubes, Gastrointestinal (And Accessories)
Regulation Number	876.5980
Product Code(s)	KNT, FAT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222880	Endolumik Gastric Calibration Tube	KNT

Device Description Summary

21 CFR 807.92(a)(4)

The Endolumik Fluorescence Guided Gastric Calibration Tube is a flexible gastric tube for use in esophageal, 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 tube is also indicated for use in esophageal surgical procedures as an esophageal bougie and to provide visualization of the tube position.

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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The EndolumikGastric 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 tube is also indicated for use in esophageal surgical procedures as an esophageal bougie and to provide visualization of the tube position.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use between the currently marketed predicate device and the subject device are identical.

The predicate device Indications for Use were updated after clearance to include identification as an esophageal bougie as this is a Class I indication which did not require a new 510(k).

Technological Comparison

21 CFR 807.92(a)(6)

The proposed Endolumik M Series Gastric Calibration Tube is identical to the predicate device with the exception that the previously cleared EGCT40 and EGCT36 models utilized LEDs of wavelengths between 697 - 766nm, which is in the visible range of the Near Infrared (NIR) spectrum. The M models utilize LEDs between wavelengths 766 and 920nm. These wavelengths are also in the NIR spectrum, and are designed for use with NIR cameras that can only visualize NIR light between 800-900nm. However, these proposed wavelengths are not visible to the human eye, so one additional 520nm (green visible light) LED was added to give users a positive indication that the product had been powered on.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following tests were performed to evaluate the substantial equivalence. All tests passed.
IEC 60601-2
IEC 60601-2 Section 5
IEC 60601-1
IEC 60601-2-18
IEC 62471