May 6, 2024

Boehringer Laboratories, LLC
Ondrej Nikel, Ph.D.
New Product Development Engineer
300 Thoms Drive
Phoenixville, PA 19460

Re: K234033
Trade/Device Name: ViSiGi LUX (5332); ViSiGi LUX (5336); ViSiGi LUX (5340)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: March 28, 2024
Received: March 28, 2024

Dear Ondrej Nikel:

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, PhD, MBA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234033

Device Name

ViSiGi LUX (5332);
ViSiGi LUX (5336);
ViSiGi LUX (5340)

Indications for Use *(Describe)*

ViSiGi® LUX 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.

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

27th March, 2024

2. SUBMITTER

Applicant:	Boehringer Laboratories, LLC 300 Thoms Dr Phoenixville, PA 19460 United States
Official Contact:	Ondrej Nikel New Product Development Engineer Phone: (484) 383 5870 Email: onikel@boehringelabs.com

3. DEVICE INFORMATION

Trade Name:	ViSiGi LUX (5332); ViSiGi LUX (5336); ViSiGi LUX (5340)
510(k) Submission:	K234033
Common Name:	Gastrointestinal tube
Device Classification:	Tubes, Gastrointestinal (and Accessories)
Regulation:	21 CFR 876.5980
Product Code:	KNT
Class:	II

4. PREDICATE DEVICE INFORMATION

Trade Name:	Boehringer Laboratories ViSiGi® 3D
510(k) Submission:	K130483
Common Name:	Gastrointestinal tube and accessories
Device Classification:	Tubes, Gastrointestinal (and Accessories)
Regulation:	21 CFR 876.5980
Product Code:	KNT
Class:	II

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5. Reference Device Information

Trade Name:	Endolumik Fluorescence Guided Gastric Calibration Tube (FG Bougie)
510(k) Submission:	K222880
Common Name:	Gastrointestinal tube and accessories
Device Classification:	Tubes, Gastrointestinal (and Accessories)
Regulation:	21 CFR 876.5980
Product Code:	KNT
Class:	II

6. Device Description

ViSiGi® LUX is a non-sterile, single patient use device for use in gastric and bariatric surgery. It is used to apply suction, decompress the stomach, drain gastric fluids, irrigate and to serve as a sizing guide.

The design is derived from the predicate by addition of battery-powered LED lights. The device comprises a tube with a closed, rounded tip, and holes at the distal end. The proximal end includes a slide valve, integral suction regulator and a battery case. The non-rechargeable batteries power up an array of LEDs enclosed within the distal end of the tube. The purpose of the LED lights is to aid visualization of the tube by tissue transillumination during insertion and surgery under laparoscopic vision. The device is inserted by an anesthesiologist under supervision of the surgeon. The added lights do not change the intended use and are not required for the surgery to proceed safely.

7. Indications for Use

ViSiGi® LUX 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.

8. Technological Comparison

Technological characteristics of ViSiGi® LUX are similar to its predicate. ViSiGi® LUX design uses the components of the predicate device and adds to them the battery-powered LED lights subassembly. The addition of the LED light subassembly does not change intended use or indications for use.

The technological characteristics of ViSiGi® LUX do not raise new questions of safety and effectiveness. Bench tests were conducted to establish that the function, safety, and effectiveness of ViSiGi® LUX is equivalent to the predicate device.

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9. Comparison of Technical Characteristics with the Predicate Device

Device	ViSiGi® LUX Subject Device	ViSiGi® 3D Predicate (K130483)	Comparison
Class	II	II	Same
Product code and Regulation	KNT, 876.5980	KNT, 876.5980	Same
Indications for use	The Boehringer laboratories ViSiGi® LUX 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.	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.	Same
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, irrigation, sizing	Suction, drainage, irrigation, sizing	Same
Technical/Performance Characteristics			
Outer Diameter /French size	32F, 36F, 40F	32F, 36F, 40F	Same
Length	1067 mm	1067 mm	Same
Tubing	Single lumen with rounded, closed distal end	Single lumen with rounded, closed distal end	Same
Distal Side Holes	Yes	Yes	Same
Connector for Suction	Yes	Yes	Same
Slide Valve	Yes	Yes	Same
Tubing Material	Styrene-Ethylene-Butylene-Styrene (SEBS block copolymer)	Styrene-Ethylene-Butylene-Styrene (SEBS block copolymer)	Same
Markings	Yes	Yes	Same
Sterility	Supplied non-sterile, disposable, single patient use	Supplied non-sterile, disposable, single patient use	Same
LED lights	No	Yes	Different, equivalence established via testing

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10. NON-CLINICAL AND/OR CLINICAL TEST SUMMARY

The tests listed below were conducted to support Substantial equivalence of ViSiGi® LUX:

- Cytotoxicity Test, ISO Elution Method per ISO 10993-5
- Guinea Pig Maximization Sensitization Test, Polar and Non-polar Extraction per ISO 10993-10
- Intracutaneous Irritation Test, Polar and Non-polar Extraction per ISO 10993-23
- Basic Safety and Essential Performance Evaluation per IEC 60601-1
- Basic Safety and Essential Performance of Endoscopic Equipment per IEC 60601-2-18
- Electromagnetic compatibility (EMC) Evaluation per IEC 60601-1-2
- EMC Evaluation (RFID and common EM emitters) per AIM 7351731
- Photobiological Safety Evaluation per IEC 62471
- Packaging Integrity Test per ASTM 4169
- Visual Inspection
- Suction Testing
- Drainage Testing
- Irrigation Testing
- Dimensional Analysis
- Gastric Fluid Resistance
- Cyclic Flex Testing
- Kink Testing
- Component Integrity Testing
- Circuit Characteristics
- Thermal Characteristics

Passing these tests demonstrates substantial equivalence to the predicate device.

11. CONCLUSION

In summary, ViSiGi® LUX has the same classification and intended use as the predicate device. The technological characteristics are similar and do not raise new questions of safety and effectiveness. Passing the tests demonstrated that ViSiGi® LUX functions as well as the predicate with equivalent safety and effectiveness. In conclusion, the results support that ViSiGi® LUX is substantially equivalent to the predicate device.