January 26, 2024

Boehringer Laboratories
Nathan Simasek
Project Engineer
300 Thoms Drive
Phoenixville, Pennsylvania 19460

Re: K234145
Trade/Device Name: ViSiGi 3D Gastric Sizing Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: December 29, 2023
Received: December 29, 2023

Dear Nathan Simasek:

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
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Anthony C. Lee, MBA, PhD
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

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)*

K234145

Device Name

ViSiGi 3D Gastric Sizing Tube

Indications for Use *(Describe)*

ViSiGi 3D 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, 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.

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Section 13: Special 510(k) Summary

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

13.1 Submitter Information

Date of Submission:	29th December 2023
Applicant:	Boehringer Laboratories, LLC 300 Thoms Dr Phoenixville, PA 19460 United States
Official Contact:	Nathan Simasek Project Engineer Phone: (484) 617-1467 Email: nsimasek@boehringelabs.com

13.2 Device Information

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

13.3 Primary Predicate Information

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

13.4 Reference Device

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

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13.5 Device Description

ViSiGi® 3D is a non-sterile, single patient use device. The device comprises a tube with a closed, rounded tip, and holes at the distal end. The tubes are supplied in three separate diameters: 32 French, 36 French, and 40 French. The proximal end of ViSiGi® 3D includes an integral suction regulator and vented On/Off slide valve. The device is supplied packaged in a sealed, labeled, poly bag. A squeeze bulb with an integral pressure gauge that can connect to the proximal end of the ViSiGi® 3D tube is an optional component compatible with the ViSiGi® 3D.

ViSiGi® 3D is used during gastric and bariatric surgical procedures to aid the surgeon in modifying the patient anatomy. It is inserted into the stomach via the esophagus under supervision of the surgeon. It may be used to perform the following functions: application of suction, stomach decompression, delivery of fluids, gastric drainage, leak testing, and to serve as a sizing guide.

13.6 Intended Use

ViSiGi® 3D is intended for use in gastric and bariatric surgical procedures performed in surgery centers or hospitals. ViSiGi® 3D is indicated for the application of suction, stomach decompression, drainage of gastric fluids, irrigation, to test for leaks, and to serve as a sizing guide.

The Inclusion of "to test for leaks" for ViSiGi® 3D differs from the indication cleared for the primary predicate device in Submission K130483 and is the basis of this Special 510(k) submission. "To test for leaks" is included in the indications for use of reference device Endolumik cleared per Submission K222880. Use of ViSiGi® 3D for leak testing allows the surgeon to more efficiently assess staple line integrity intraoperatively and does not impact the procedures overall safety and effectiveness or the intended use of the device to assist in completion of gastric and bariatric surgery.

13.7 Technological Characteristics Comparison

ViSiGi® 3D is technologically identical to the primary predicate device as no design changes are required as a result of this special 510(k). The only change to the device is the addition of “to test for leaks” to the indication for use statement.

Technical/Performance Characteristics

	ViSiGi® 3D (K13048)	**ViSiGi® 3D (proposed modification)**	**Comparison**
Outer Diameter/ French Size	32F, 36F, or 40F	32F, 36F, or 40F	No Change
Inner Diameter	5.1mm, 5.6mm, or 6.4mm	5.1mm, 5.6mm, or 6.4mm	No Change
Length	Approximately 104cm	Approximately 104cm	No Change
Tubing	Single lumen with rounded, closed distal end	Single lumen with rounded, closed distal end	No Change
Distal Side Holes	Yes	Yes	No Change
Connector for Suction	Yes	Yes	No Change
Slide Valve	Yes	Yes	No Change
Balloon + Inflation Valve	No	No	No Change
Tubing Material	SEBS Thermoplastic Elastomer	SEBS Thermoplastic Elastomer	No Change

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Markings	Yes- 30, 40, and 50cm from distal tip	Yes- 30, 40, and 50cm from distal tip	No Change
Sterility	Non-sterile, disposable, single patient use	Non-sterile, disposable, single patient use	No Change
Internal Support Spring at Distal End	Yes	Yes	No Change
Kink Resistant to 90° at Distal End	Yes	Yes	No Change

13.8 Performance Data

The following performance data was collected to support the risk assessment associated with the addition of "to test for leaks" to the indications for use:

- Bulb Compatibility
- Bulb Functionality

13.9 Conclusion

The proposed addition of "to test for leaks" to the ViSiGi® 3D indications for use does not impact the classification information, intended use for completion of gastric and bariatric surgery, safety and efficacy, or technological characteristics of the primary predicate device cleared per 510(k) 130483.

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