August 14, 2026

Boehringer Laboratories, LLC
Evan Langdale
Innovation and Strategy Manager
300 Thoms Dr.
Phoenixville, Pennsylvania 19460

Re: K261890
Trade/Device Name: 52Fr ViSiGi LUX™; 52Fr ViSiGi 3D®
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: June 5, 2026
Received: June 5, 2026

Dear Evan Langdale:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Lee, Ph.D., 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261890

Please provide the device trade name(s).

52Fr ViSiGi LUX™;
52Fr ViSiGi 3D®

Please provide your Indications for Use below.

ViSiGi LUX™ 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.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K261890

510(k) Summary

Prepared on: 2026-07-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BOEHRINGER LABORATORIES, LLC
Applicant Address	300 Thoms Dr. Phoenixville PA 19460 United States
Applicant Contact Telephone	(484) 931-2395
Applicant Contact	Mr. Evan Langdale
Applicant Contact Email	elangdale@boehringerlabs.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	52Fr ViSiGi LUX™; 52Fr ViSiGi 3D®
Common Name	Gastrointestinal tube and accessories
Classification Name	Tubes, Gastrointestinal (And Accessories)
Regulation Number	876.5980
Product Code(s)	KNT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K234033	ViSiGi LUX™	KNT
K234145	ViSiGi 3D® Gastric Sizing Tube	KNT

Device Description Summary

21 CFR 807.92(a)(4)

The subject devices are non-sterile, single-patient-use gastric sizing tubes for use in gastric and bariatric surgery. They are used to apply suction, decompress the stomach, drain gastric fluids, irrigate, test for leaks, and serve as a sizing guide.

The 52 Fr devices comprise a flexible single-lumen tube with a closed, rounded distal tip, distal side holes, depth markings, a proximal slide valve, and suction connector. The larger distal tube is connected to the existing proximal assembly using an adapter component. ViSiGi LUX™ also includes non-rechargeable batteries that power 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 devices are inserted by an anesthesiologist under supervision of the surgeon. The devices do not incorporate software or firmware.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

ViSiGi LUX™ 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.

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed indications include leak testing for ViSiGi LUX™, which was not included in K234033. Leak testing was previously cleared for ViSiGi 3D® under K234145. ViSiGi LUX™ is the lighted version of ViSiGi 3D®, and the leak testing function is performed in the same manner for both devices using the same slide valve and optional squeeze bulb connection. Therefore, adding leak testing to ViSiGi LUX™ does not create a new intended use.

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices are 52 Fr versions of the ViSiGi 3D® and ViSiGi LUX™ gastric sizing tube product lines. Compared to the ViSiGi LUX™ predicate device, the subject devices have the same classification, product code, regulation, use environment, patient population, intraoperative use, tubing material, single-lumen configuration, rounded closed distal tip, distal side holes, suction connector, slide valve, depth markings, and non-sterile single-patient-use configuration.

The technological differences are limited to the larger 52 Fr distal tube size and the associated adapter component needed to connect the larger distal tube to the existing proximal assembly. The 52 Fr ViSiGi LUX™ retains the same battery-powered lighted distal end feature as the predicate ViSiGi LUX™ device. These differences do not change the device's fundamental technological characteristics or principle of operation.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing was performed to support the 52 Fr size modification. Irrigation Testing, Dimensional Analysis, Bulb Compatibility Testing, Bulb Functionality Testing, ,Squeeze Bulb Verification Testing, and Fr Kink Resistance testing conducted on 52 Fr size modification. Component integrity testing was conducted on the new adapter/tubing connection used to connect the larger 52 Fr distal tube to the existing proximal assembly.

Sixty samples were tested against a predetermined tensile-force acceptance criterion. All samples met the acceptance criterion, supporting that the modified 52 Fr ViSiGi 3D® and ViSiGi LUX™ devices maintain appropriate mechanical integrity for the added 52 Fr size option.

No clinical testing was performed. Based on the non-clinical testing, risk analysis, and comparison to the predicate devices, the subject devices are substantially equivalent to the predicate device.