



July 2, 2025

Boehringer Laboratories, LLC
William Dackis
Project Engineer
300 Thoms Dr
Phoenixville, Pennsylvania 19460

Re: K243399

Trade/Device Name: Boehringer Laboratories Liver Retractor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 3, 2025
Received: June 3, 2025

Dear William Dackis:

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.

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,

**James H.
Jang -S**

Digitally signed by
James H. Jang -S
Date: 2025.07.02
13:15:07 -04'00'

James Jang, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K243399

Device Name
Boehringer Laboratories Liver Retractor

Indications for Use (Describe)

The Boehringer Laboratories Liver Retractor is indicated for use in laparoscopic surgical procedures to elevate the liver, improve access to surgical sites, and provide visualization of target anatomy.

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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2. This 510(k) summary was prepared in accordance with 21 CFR 807.92.

2.1 DATE

July 1st, 2025

2.2 SUBMITTER

Applicant: Boehringer Laboratories, LLC
300 Thoms Dr
Phoenixville, PA 19460
United States

Official Contact: William Dackis
Engineering Manager
Phone: (484) 931 2364
Email: wdackis@boehringerlabs.com

2.3 DEVICE INFORMATION

Trade Name: Boehringer Laboratories Liver Retractor

Common Name: Retractor

Review Panel: General & Plastic Surgery
Regulation: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Product Code: GCJ
Device Class: II

2.4 PREDICATE DEVICE INFORMATION

Trade Name: LiVac® Retractor System

Common Name: Retractor

510(k) Number: K162445
Regulation: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Product Code: GCJ
Class: II

Boehringer Laboratories, LLC

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2.5 DEVICE DESCRIPTION

The Boehringer Laboratories Liver Retractor is comprised of three components: a Suction Delivery Assembly, a Positioning Clip, and an Integral Suction Regulator. The suction delivery assembly is composed of a Flexible Tube with a proximal Suction Cup and a distal Grasping Suture.

The suction delivery assembly is introduced into the abdomen via a standard laparoscopic trocar. A standard suture passer is then used to grip the grasping suture and pull the upper portion of the flexible tube percutaneously through the abdominal wall. The now externalized tip of the flexible tube is cut off and the open end is connected to the integral suction regulator. The conformable suction cup can then be applied laparoscopically to the liver and the external portion of the flexible tube manipulated to adjust liver position. Once at the desired height, the positioning clip is placed around the external portion of the flexible tube and against the skin to lock the device in place. The suction cup can be efficiently repositioned via laparoscopic technique to accommodate the evolving requirements of a procedure. The device is inserted, manipulated, and removed by or under the direct supervision of a surgeon.

2.6 INDICATIONS FOR USE

The Boehringer Laboratories Liver Retractor is indicated for use in laparoscopic surgical procedures to elevate the liver, improve access to surgical sites, and provide visualization of target anatomy.

2.7 TECHNOLOGICAL COMPARISON

The Boehringer Laboratories Liver Retractor shares several technological characteristics with the predicate device, including the utilization of suction, conformable materials of construction, and design for laparoscopic use. Unlike the predicate, the subject device includes a non-adjustable integral suction regulator that is factory set to a lower suction setpoint.

The technological characteristics of the Boehringer Laboratories Liver Retractor do not raise new questions of safety and effectiveness. Bench testing and an animal safety study were conducted to establish that the function, safety, and effectiveness of the Boehringer Laboratories Liver Retractor were equivalent to the predicate device.



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2.8 COMPARISON OF TECHNICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Category	Boehringer Laboratories Liver Retractor Subject Device	LiVac® Retractor System Predicate Device
Device Sponsor	Boehringer Laboratories, LLC	LiVac Pty Ltd
510(k) No.	K243399	K162445
Product Code	GCJ	GCJ
Device Class	II	II
Regulation No.	876.1500	876.1500
Regulation Description	Endoscope and accessories	Endoscope and accessories
Indications for Use	The Boehringer Laboratories Liver Retractor is indicated for use in laparoscopic surgical procedures to elevate the liver, improve access to surgical sites, and provide visualization of target anatomy.	The LiVac® Retractor is designed as an organ and tissue retractor for use in laparoscopic procedures to elevate organs and tissue to provide improved access and visualisation of surgical sites.
Prescription Use	Yes	Yes
Body Location	Abdominal	Abdominal
Target Area	Liver	Liver and other organs and tissues.
Single Use	Yes	Yes
Supplied Sterile	Yes (Gamma)	Yes (Gamma)



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<p>Device Description</p>	<p>The Boehringer Laboratories Liver Retractor is a soft, oval polyurethane cup connected to suction tubing. The suction tubing is pulled through the abdominal wall percutaneously where it is connected to an integral suction regulator. The regulator is then connected to a suction source via standard (sterile) medical suction tubing. An external clip is used to hold the device in place at the desired retraction position. The Boehringer Laboratories Liver Retractor is compatible with laparoscopic ports ≥ 12 mm in size and does not require unique tooling or novel methods for deployment.</p>	<p>The LiVac[®] Retractor is a soft silicone ring connected to suction tubing. The suction tubing is connected to a large calibre external (sterile) suction hose via the LiVac[®] Connector. The LiVac[®] Retractor can be used as a standalone device with a laparoscopic multi-channel single port or with a 12-15 mm laparoscopic port. The LiVac[®] Bevel accessory is used to facilitate use of the LiVac[®] Retractor with a 10-12 mm “Hasson” type port inserted at the umbilicus.</p>
<p>Mode of Operation or Technical Characteristics</p>	<p>Suction (negative pressure) applied to the device by an external suction source by way of a suction hose/adaptor in the facility; i.e., vacuum technology.</p>	<p>Suction (negative pressure) applied to the device by an externally regulated suction source by way of a suction hose/adaptor in the facility; i.e., vacuum technology.</p>
<p>Operational Vacuum Pressure</p>	<p>280-360 mmHg (non-adjustable, self-regulated)</p>	<p>300-600 mmHg (user-adjusted, external regulator reliant)</p>
<p>Materials</p>	<p>Soft polyurethane cup with embedded foam connected to flexible suction tubing with a suture at the distal tip. All internal materials are soft and flexible plastics. External components include a factory set suction regulator and nylon positioning clip.</p>	<p>Soft silicone ring connected to suction tubing. Optional accessory bevel (modified Hasson design). Both material and design are flexible. Rigid connector used through or alongside port.</p>



2.9 NON-CLINICAL TEST SUMMARY

The tests listed below were conducted to support substantial equivalence of the Boehringer Laboratories Liver Retractor:

- GLP Compliant Live Animal Safety Study
- Biocompatibility Testing per ISO 10993-1/-5/-10/-11/-23
- Sterilization Validation per ISO 11137-1/-2/-3, and ISO 11373-1/-2
- Packaging Integrity Testing per ASTM D4332, ASTM D7386, ASTM F2096, ASTM F88/F88M
- Boehringer Laboratories Liver Retractor Performance Testing to demonstrate device retraction times
- Device Integrity Test
- Regulator Functionality Test
- Shelf life/Stability Test (Accelerated Aging)

Passing these tests demonstrates substantial equivalence to the predicate device.

2.10 CONCLUSION

In summary, the Boehringer Laboratories Liver Retractor 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 above tests demonstrated that the Boehringer Laboratories Liver Retractor functions as well as the predicate with equivalent safety and effectiveness and that the chosen packaging method maintains the sterility of the device within the proposed shelf life.

In conclusion, the results presented in this updated submission support the substantial equivalence of the Boehringer Laboratories Liver Retractor to the predicate device.