



Food and Drug Administration
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Silver Spring, MD 20993-0002

September 11, 2015

Boehringer Laboratories, LLC
Mr. Christopher Radl
Engineering, Product Development Manager
300 Thoms Drive
Phoenixville, Pennsylvania 19460

Re: K151990
Trade/Device Name: Tissue Removal System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 17, 2015
Received: July 20, 2015

Dear Mr. Radl:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151990

Device Name

Tissue Removal System

Indications for Use (Describe)

The Tissue Removal System is indicated for the contained removal of tissue, including contained manual tissue sectioning, during minimally invasive surgical procedures.

Contraindications:

The Tissue Removal System is contraindicated for laparoscopic power morcellation during gynecologic procedures.

The Tissue Removal System is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

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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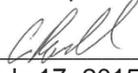
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510(k) Summary

Prepared: July 17, 2015

APPLICANT INFORMATION:

Name: Boehringer Laboratories, LLC
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Phoenixville, PA 19460
Phone: 610-278-0900
Fax: 610-278-0907
Contact: Christopher Radl; Engineering, Product Development Manager

Signature: 
Date: July 17, 2015

TRADE NAME:

Tissue Removal System

COMMON NAME:

Laparoscopic Retrieval System

DEVICE CLASSIFICATION:

Accessory to Endoscope, Class II
Product Code: GCJ
Regulation: 876.1500 Endoscope and Accessories
Classification Panel: General & Plastic Surgery

PREDICATE DEVICES:

Predicate: Tissue Removal Pouch K150781

DEVICE DESCRIPTION:

The Tissue Removal System is comprised of the Tissue Removal Pouch cleared under K150781 and an additional accessory Sectioning Device. It is provided sterile, and is for single patient use.

The Tissue Removal Pouch of the Tissue Removal System includes a bag with a single large opening held open by a thin, opening ring. During laparoscopic surgery, the bag is placed within the peritoneal space via an existing port site. Tissue that has been resected is placed within the bag for isolation, containment and removal from the patient. The bag opening is exteriorized. Two halves of the Tissue Removal Pouch flip ring are attached to each other and to the bag opening. The bag is rolled around the flip ring by inverting the flip ring, in order to draw the resected tissue toward the port site.

The resected tissue is then removed en bloc (for smaller specimens), or by first dividing the specimen using the accessory Sectioning Device. The Sectioning Device is comprised of a blunt wire, a flexible passer and a handle with a blunt hook. The passer is used to encircle the specimen with the wire. The handle includes a blunt hook that can be used to aid in the advancement of the passer. The specimen is divided by the manual application of a back and forth motion to the wire. Use of the accessory Sectioning Device permits division of the specimen while maintaining the containment effectiveness of the Tissue Removal Pouch

INTENDED USE:

The Tissue Removal System is intended for the containment and removal of tissue during minimally invasive surgical procedures.

COMPARISON SUMMARY:

The Tissue Removal System is identical to the predicate Tissue Removal Pouch with the exception of the accessory Sectioning Device. With the predicate Tissue Removal Pouch, the only way to divide large specimens for removal was with the use of sharp instruments such as scalpels. In comparison, the accessory Sectioning Device of the Tissue Removal System allows for specimen division with the use of a blunt wire.

NON-CLINICAL TESTING:

The following non-clinical tests have been included with this submission:

- **Simulated Use Testing** followed by Bubble Leak, Dye Penetration and Viral Barrier Testing, demonstrating that the Tissue Removal System performs as intended and that the Tissue Removal Pouch maintains containment integrity after use with the accessory Sectioning Device.
- **Extreme Use Testing** followed by Bubble Leak, Dye Penetration and Viral Barrier Testing, demonstrating that the Tissue Removal System maintains its integrity and containment effectiveness after sectioning of multiple tissue specimens, far in excess of actual clinical conditions.
- **Sectioning Device Puncture Resistance Testing** demonstrating that the flexible passer of the Sectioning Device will not puncture the Tissue Removal Pouch of the Tissue Removal System.
- **Sectioning Device Hook Tear Resistance Testing** demonstrating that the blunt hook of the hooked handle will not tear the Tissue Removal Pouch of the Tissue Removal System.
- **Film Cutting Testing** demonstrating that forcing the wire of the Sectioning Device into the film of the Tissue Removal Pouch does not result in a cut to the Tissue Removal Pouch.

CONCLUSIONS:

As evidenced by the provided information, the Tissue Removal System is as safe and effective as, and performs as well as, or better than, the legally marketed predicate device.