DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2015

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

Re: K150781
Trade/Device Name: Tissue Removal Pouch
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 10, 2015
Received: June 10, 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,

Jennifer R. Stevenson -S

For 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150781

Device Name

Tissue Removal Pouch

Indications for Use *(Describe)*

The Tissue Removal Pouch is indicated for the removal of tissue during surgical procedures and for the containment of tissue during extracorporeal manual morcellation.

Contraindications:

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

The Tissue Removal Pouch 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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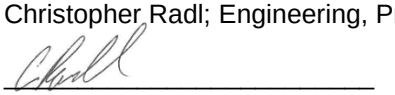
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared: June 9, 2015

APPLICANT INFORMATION:

Name: Boehringer Laboratories, LLC
Address: 300 Thoms Drive
Phoenixville, PA 19460
Phone: 610-278-0900
Fax: 610-278-0907
Contact: Christopher Radl; Engineering, Product Development Manager

Signature: 
Date: June 9, 2015

TRADE NAME:

Tissue Removal Pouch

COMMON NAME:

Laparoscopic Retrieval Device

DEVICE CLASSIFICATION:

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

PREDICATE DEVICES:

Primary Predicate:	Applied Medical Tissue Containment System	K142427
Additional Predicate:	Applied Medical Specimen Retrieval System	K060051

DEVICE DESCRIPTION:

The Tissue Removal Pouch includes a polymer film bag, a flip ring packaged in two halves, and a guard. It is provided sterile and is for single patient use.

The bag has 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 and removal from the patient. The bag opening is then exteriorized. The two halves of the 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 extracorporeal manual morcellation (for larger specimens). The guard may be used to protect the bag during manual morcellation. The bag is removed following the removal of sufficient tissue to enable the bag to be pulled out through the port site.

INTENDED USE:

The Tissue Removal Pouch is indicated for the removal of tissue during surgical procedures and for the containment of tissue during extracorporeal manual morcellation.

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

The Tissue Removal Pouch 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.

COMPARISON SUMMARY:

The Tissue Removal Pouch and predicate devices are intended for tissue containment and removal during laparoscopic surgery. All devices are single use, and sterile, with a biocompatible polymer film bag portion, that has a single opening incorporating an opening mechanism. Furthermore, the bag portion of all devices is inserted into the peritoneal cavity of the patient, loaded with a specimen, and exteriorization. All devices provide some mechanism to assist in the removal of the bag and the specimen.

The following aspects involve slight differences between the Tissue Removal Pouch and one or both of the predicate devices:

- Mechanism of bag insertion
- Mechanism of bag exteriorization
- Morcellation protection
- Bag volume

NON-CLINICAL TESTING:

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

- Film Impermeability Testing:
  Verifies film impermeability.
- Bubble Leak Testing:
  Demonstrates that the bag of the Tissue Removal Pouch is leak free.
- Weld Strength Testing:
  Demonstrates adequate weld strength.
- Puncture Resistance Testing:
  Demonstrates adequate resistance to puncture.
- Burst Testing:
  Demonstrates adequate burst strength.
- Opening Ring Pull Testing:
  Demonstrates adequate pull strength.
- Guard Cut Resistance Testing:
  Demonstrates adequate resistance to cutting.
- Simulated Use Testing
  Demonstrates that the Tissue Removal Pouch performs as intended.
- Biocompatibility Testing
  Demonstrates that the device is biocompatible.
- Dye Penetration Testing
  Demonstrates that the Tissue Removal Pouch is leak free.
- Viral Penetration Testing
  Demonstrates that the Tissue Removal Pouch is and adequate barrier to cellular migration.

CONCLUSIONS:

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