K130483

# 4. 510(k) Summary

Prepared: February 11, 2013

MAR 28 2013

## APPLICANT INFORMATION:


Name: Boehringer Laboratories, Inc.
Address: 300 Thoms Drive
Phoenixville, PA 19460
Phone: 610-278-0900
Fax: 610-278-0907
Contact: Christopher Radl; Engineering, Product Development Manager
Signature: Christopher Radl 1/23/13


## TRADE NAME:

Boehringer Laboratories Gastric Sizing Tube

## COMMON NAME:

Gastrointestinal Tube and accessories

## DEVICE CLASSIFICATION:

Class II
Product Code: KNT
Regulation: 876.5980
Classification Panel: General & Plastic Surgery

## PREDICATE DEVICES:

| | |
|---|---|
| REALIZE™ Gastric Calibration Tube | K071764 |
| EndoFLIP® Gastric Tube EF-900 | K110529 |

## DEVICE DESCRIPTION:

The Boehringer Laboratories Gastric Sizing Tube is a single patient use, non-sterile device which consists of a 76 cm long, thermoplastic elastomer (Styrene-Ethylene-Butylene-Styrene) tube of either 32 French, 36 French, or 40 French diameter, with a low density polyethylene (LDPE) slide valve-connector at the proximal end of the tube. The tube has multiple holes and a rounded end, distal from the slide valve, and contains a stainless steel support spring inside the lumen of the tube at the distal end.

The device is used to decompress the stomach, remove stomach contents, and allow for irrigation via the distal holes. The slide valve is used to switch between open for suction/irrigation and closed/vent. The tube serves as a sizing guide.

## INTENDED USE:

The Boehringer Laboratories Gastric Sizing Tube is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to serve as a sizing guide.

## COMPARISON SUMMARY

| Device | Boehringer Laboratories Gastric Sizing Tube | Predicate REALIZE™ Gastric Calibration Tube K071764 | Predicate EndoFLIP® Gastric Tube EF-900 K110529 |
|---|---|---|---|
| **Manufacturer** | Boehringer Laboratories | Obtech Medical Sarl / Ethicon Endo-Surgery Inc | Crospon |
| **Intended Use** | | | |
| **Indications for Use Statement** | The Boehringer Laboratories Gastric Sizing Tube is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to serve as a sizing guide. | The Gastric Calibration tube is indicated for use in gastric and bariatric surgical procedures to provide visible and tactile delineation of the antrum of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid and size a gastric pouch. | The EndoFLIP® EF-900 Gastric Tube is intended for use in bariatric surgical procedures to provide a sized support bougie, and to permit stomach decompression, gastric fluid drainage and removal. It is also intended for use to aid deployment of EndoFLIP® EF-620, EF-325 and B-325 catheters. |
| **Typical Use** | Gastric and bariatric procedures | Gastric and bariatric procedures | Gastric and bariatric procedures |
| **Environments of Use** | Surgery centers, hospitals | Surgery centers, hospitals | Surgery centers, hospitals |
| **Patient Population** | Individuals undergoing bariatric and/or gastric procedures | Individuals undergoing bariatric and/or gastric procedures | Individuals undergoing bariatric and/or gastric procedures |
| **Intraoperative Use** | Yes | Yes | Yes |
| **Functions** | Suction, drainage, sizing, irrigation | Suction, drainage, sizing, irrigation | Suction, drainage, sizing, irrigation, deployment of EndoFLIP® catheter |
| **Technical/Performance Characteristics** | | | |
| **Outer Diameter / French size** | 32F, 36F, or 40F | 38F | 43F |
| **Length** | 76 cm | 74.5 cm | 75 cm |
| **Tubing** | Single lumen with rounded, closed distal end | Single lumen with rounded, closed distal end | Single lumen with open distal end |
| **Distal Side Holes** | Yes | Yes | Yes |
| **Connector for Suction** | Yes | No | Yes |
| **Slide Valve** | Yes | No | No |
| **Balloon + Inflation Valve** | No | Yes | No |
| **Tubing Material** | Styrene-Ethylene-Butylene-Styrene (SEBS Co-polymer) | Silicone | PVC with Duraglide PTFE coating |
| **Markings** | No markings. | Markings are provided with the zero reference located approximately 40 cm from the proximal end of the balloon. | Includes a mark at 20 cm and 70 cm from the distal end. |
| **Sterility** | Supplied non-sterile, disposable, single patient use | Supplied non-sterile, disposable, single patient use | Supplied non-sterile, disposable, single patient use |

## PERFORMANCE/NON-CLINICAL TESTING:

The following non-clinical performance testing has been submitted, referred to, or relied on in this 510k submission:

- Dimensional Analysis
- Valve-Connector to Tube Joint Strength Test
- Tube Distal End Kink Test
- Support Spring to Tube Stability Test
- Age Test
- ISO 80369-1:2010 - Small-bore connectors for liquids and gases in healthcare applications - Part 1: General Requirements Compliance
- Suction Tubing Fitting Connector Test

- Cytotoxicity study per AAMI/ANSI/ISO 10993-5: 2009 - Biological Evaluation of Medical Devices Part 5: Tests for *in vitro* cytotoxicity.
- Intracutaneous study per AAMI/ANSI/ISO 10993-10: 2010 - Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization.
- Maximization Sensitization study per AAMI/ANSI/ISO 10993-10: 2010 - Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization.

## DISCUSSION:

The Boehringer Laboratories Gastric Sizing Tube is similar to the predicate devices REALIZE™ Gastric Calibration Tube and EndoFLIP® Gastric Tube EF-900.

**Intended Use**
The indications for use statement for the Boehringer Laboratories Gastric Sizing Tube contains language that is not specifically incorporated in the indications for use statements of the predicate device. Specifically the Boehringer Laboratories Gastric Sizing Tube indication for use statement includes "for the application of suction" and "irrigation".

While the exact text "for the application of suction" is not specifically included in the Indications for Use statements of the predicate devices it is inherent in the functions of stomach decompression and removal of gastric fluid, which are included in the indication for use statements of the predicate devices. Additionally, suction is referred to in the description section of the 510k Summary for the REALIZE™ Gastric Calibration Tube and the description section of the REALIZE™ Gastric Calibration Tube Instructions for Use, as well as in the Device Description section of the EndoFLIP® Gastric Tube EF-900 510k summary.

While "irrigation" is not specifically included in the Indications for Use statements of the predicate devices, it is specifically covered in the Description Section of the 510k Summary for the REALIZE™ Gastric Calibration Tube and the Description Section of the REALIZE™ Gastric Calibration Tube Instructions for use, as well as in the Device Description section of the EndoFLIP® Gastric Tube EF-900 510k summary.

As such, these differences do not affect the safety and effectiveness of the new device when used as labeled.

**Technical Characteristics**
The Boehringer Laboratories Gastric Sizing Tube has technological characteristics similar to the predicate devices. The tubes are made from different materials, however, the materials of the Boehringer Laboratories Gastric Sizing Tube and the predicate devices are all biocompatible. The Boehringer Laboratories Gastric Sizing Tube includes a slide valve, while the predicate devices do not. The slide valve enables the user to more easily turn suction on and off. The predicate devices include markings on the tube, while the Boehringer Laboratories Gastric Sizing Tube does not, as it is inserted under laparoscopic visualization. Lastly, the Boehringer Laboratories Gastric Sizing Tube includes an internal support spring at the distal end which provides the device with increased resistance to kinking. These differences do not affect the safety and effectiveness of the new device when used as labeled.

**Performance Testing**
The performance testing conducted with the Boehringer Laboratories Gastric Sizing Tube referenced above indicates the new device performs equivalently to, or better than the predicate devices.

## CONCLUSION:

As evidenced from the intended use, technological characteristics, and performance testing conducted, the Boehringer Laboratories Gastric Sizing Tube is as safe, as effective, and performs as well as the predicate devices.

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

March 28, 2013

BOEHRINGER LABORATORIES, INC.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K130483
Trade/Device Name: Boehringer Laboratories Gastric Sizing Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: March 14, 2013
Received: March 15, 2013

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -S

*Acting Director for:*
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## 3. Indications for Use Form

510(k) Number (if known): K130483
Device Name: Boehringer Laboratories Gastric Sizing Tube
Indications for Use:

The Boehringer Laboratories Gastric Sizing Tube is indicated for use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to serve as a sizing guide.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130483