



Food and Drug Administration
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May 4, 2016

Covidien LLC
Rebecca Magnanimo
Regulatory Affairs Product Specialist
60 Middletown Ave.
North Haven, CT 06473

Re: K160654
Trade/Device Name: GastriSail™ Gastric Positioning System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: April 7, 2016
Received: April 13, 2016

Dear Rebecca Magnanimo:

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" (21 CFR 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,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)

K160654

Device Name

GastriSail™ Gastric Positioning System

Indications for Use (Describe)

The GastriSail™ Gastric Positioning System is indicated for use in gastric and bariatric surgical procedures for the application of suction, decompression and to radially expand the stomach, to drain gastric fluids, to test for leaks, to provide visible and tactile delineation of the lesser curvature of the stomach and to serve as a sizing guide for gastric and bariatric procedures, such as sleeve gastrectomy.

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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510(k) Summary

SUBMITTER: Covidien llc
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DATE PREPARED: 02/22/16

PRODUCT CODE: KNT

REGULATION NUMBER: 21CFR 876.5980

TRADE/PROPRIETARY NAME: GastriSail™ Gastric Positioning System

COMMON/USUAL NAME: Gastric Positioning System

CLASSIFICATION NAME: Tubes, Gastrointestinal (and Accessories)

PREDICATE DEVICES: GastriSail™ Gastric Positioning System (K143088)

DEVICE DESCRIPTION: The GastriSail™ Gastric Positioning System is a 40FR flexible, non-sterile, single-use, dual lumen gastric tube designed to be inserted into the esophagus by an anesthesiologist for use in gastric and bariatric surgical procedures, such as sleeve gastrectomy.

The GastriSail™ Gastric Positioning System consists of a dual lumen flexible tube. One lumen houses the Sail feature and integrated LED guidelights, and the other lumen has rows of distal holes which, when connected to suction provides vacuum to the stomach for evacuation of stomach contents and suction fixation along the lesser curvature of the stomach. This lumen is also used to perform leak testing at the end of the procedure.

INDICATIONS FOR USE: The GastriSail™ Gastric Positioning System is indicated for use in gastric and bariatric surgical procedures for the application of suction, decompression and to radially expand the stomach, to drain gastric fluids, to test for leaks, to provide visible and tactile delineation of the lesser curvature of the stomach and to serve as a sizing guide for gastric and bariatric procedures, such as sleeve gastrectomy.

SUMMARY COMPARING
THE TECHNOLOGICAL
CHARACTERISTICS OF THE
SUBJECT AND PREDICATE
DEVICES:

Modifications to design of the current GastriSail™ Gastric Positioning System (K143088) has created a new product to be launched as the proposed GastriSail™ Gastric Positioning System 40 Fr/Ch (13.3mm).

The changes include a change in the size of diameter of the lumen flexible tubing from a 36 Fr/Ch (12.0mm) (predicate) to a 40 Fr/CH (13.3mm)(proposed) size. Increasing tube diameter by (1.3mm).

Additionally, there will also be a material change to the previously cleared 36 Fr/Ch GastriSail™ Gastric Positioning System (K143088). The tip material for the 36Fr/Ch and 40Fr/Ch will be changing from a polycarbonate to a Silastic Silicone material.

The proposed GastriSail™ Gastric Positioning System 40 Fr/Ch (13.3mm) was evaluated for the following:

- Biocompatibility testing was conducted to evaluate proposed tip material change from polycarbonate to silastic silicone in accordance with ISO 10993-1:2009.
- Stability testing was conducted to evaluate proposed tip material change from polycarbonate to silastic silicone.
- Performance studies (nonclinical testing) was conducted to demonstrate that the proposed device, is substantially equivalent to the predicate device.

NONCLINICAL TESTING

Non Clinical testing that supports the intended use of this device includes:

- Visual Inspection
- Dimensional Measurement
- Vacuum Pressure Evaluation
- Tensile Test Evaluation
- Battery Test

IN VIVO TESTING

In vivo testing that supports the intended use of this device includes:

- Evaluation of esophageal insertion test in porcine

GastriSail™ Gastric Positioning System is sold nonsterile therefore sterility is not required. Only Non Clinical Testing was performed for the proposed changes therefore, clinical testing was not performed or relied on for a determination of substantial equivalence.

CHARACTERISTICS	Proposed GastriSail™ Gastric Positioning System	K143088 GastriSail™ Gastric Positioning System
IFU	The GastriSail™ Gastric Positioning System is indicated for use in gastric and bariatric surgical procedures for the application of suction, decompression and to radially expand the stomach, to drain gastric fluids, to test for leaks, to provide visible and tactile delineation of the lesser curvature of the stomach and to serve as a sizing guide for gastric and bariatric procedures, such as sleeve gastrectomy.	The GastriSail™ Gastric Positioning System is indicated for use in gastric and bariatric surgical procedures for the application of suction, decompression and to radially expand the stomach, to drain gastric fluids, to test for leaks, to provide visible and tactile delineation of the lesser curvature of the stomach and to serve as a sizing guide for gastric and bariatric procedures, such as sleeve gastrectomy.
Length of tube	132 cm (total)	132 cm (total)
Tubing	Multi lumen with rounded, closed distal end	Multi lumen with rounded, closed distal end
Size	40 FR	36 Fr
Sterility	Clean, Non Sterile, single-patient use	Clean, Non Sterile, single-patient use
Suction fixation	Yes	Yes
Decompression capability	Yes	Yes
Sail feature	Yes	Yes
LED Guide lights	Yes	Yes
Disposable	Yes	Yes
Tip Material	Silastic Silicone	Polycarbonate

CONCLUSION:

The results of testing demonstrate that the modified GastriSail™ Gastric Positioning System 40 Fr/Ch (13.3mm) is substantially equivalent to the legally marketed GastriSail™ Gastric Positioning System (K143088).