DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 23, 2015

Medical Innovation Development
% Mélanie Fouilland
Quality/RA Manager
9, Chemin Du Jubin
Dardilly, RHONE 69570
France

Re: K142548
Trade/Device Name: MIDSLEEVE™ Calibration Tube for Sleeve Gastrectomy
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 11, 2015
Received: May 14, 2015

Dear Mélanie Fouilland,

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,

Herbert P. Lerner -S

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

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)*
K142548

Device Name
MIDSLEEVE Calibration Tube for Sleeve Gastrectomy

Indications for Use *(Describe)*
MIDSLEEVE, Calibration Tube for Sleeve Gastrectomy is indicated for use in the bariatric procedure known as Longitudinal Sleeve Gastrectomy (LSG), to drain and remove gastric fluid and to provide a calibration of the gastric pouch.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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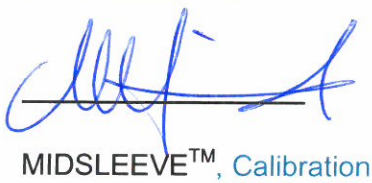
SECTION 6 : 510(k) SUMMARY

Prepared:	September 3rd, 2014
Updated:	June 19th, 2015
Applicant information:	Medical Innovation Développement
Address:	9, Chemin du Jubin 69570 DARDILLY FRANCE
510(k) Number :	K142548
Telephone Number:	+334 78 17 48 04
Fax Number:	+334 72 82 91 23
Name of Contact Person:	Mélanie FOUILLAND Quality/RA Manger
E-mail address	mid@midband.fr
Signature	
Trade Name:	MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy
Common Name:	Gastrointestinal tube and accessories
Device classification:	Class II
Product Code:	KNT
Regulation Number:	21 CFR 876.5980

Predicate Devices:	REALIZE™ Calibration Tube	K071764
	Boehringer Laboratories Gastric Sizing Tube	K130483

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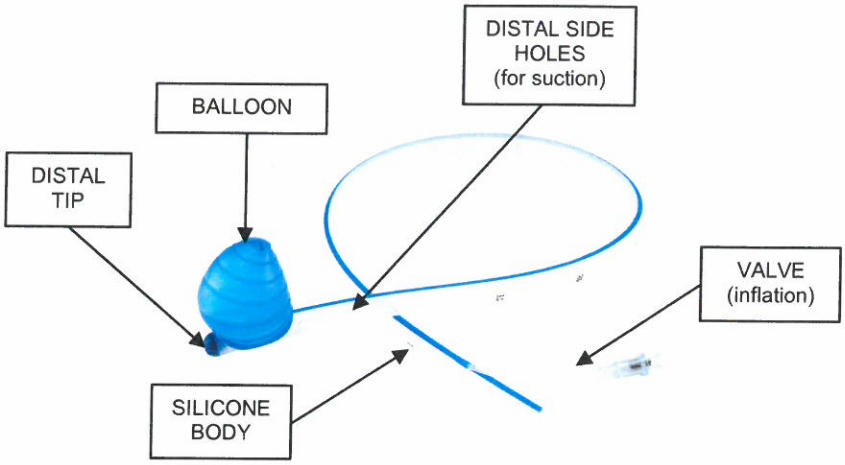
1. Device Description

MIDSLEEVE™ Calibration tube for Sleeve Gastrectomy is a sterile, single use medical device which consists of a 900 mm long, silicone tube of 37.5 French diameter, with a PVC valve at the proximal end of the tube. The tube has several holes and a rounded end, distal from the valve and an asymmetric balloon which can be filled through the valve. Reference markings are provided on the tube, from the distal end to 70 cm to locate the tube position.



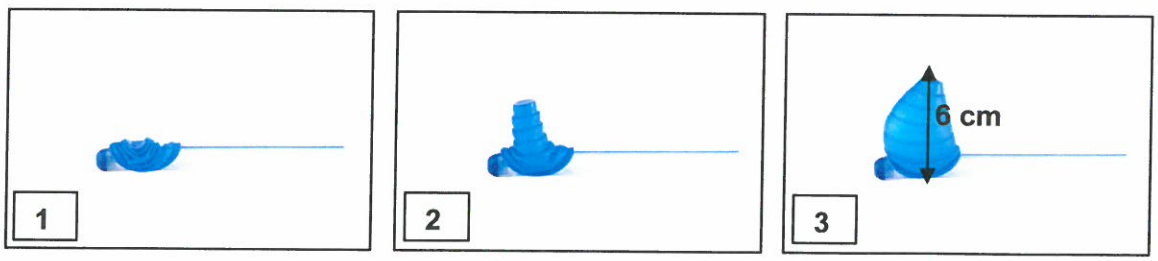
1.1 Intended use

MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy is indicated for use in the bariatric procedure known as Longitudinal Sleeve Gastrectomy (LSG), to drain and remove gastric fluid and to provide a calibration of the gastric pouch.

1.2 Principles of operation

The balloon is initially deflated and in contact with the silicone body (see 1. below), which enables the insertion of the tube inside the throat to reach the patient's stomach.

As air or saline solution is injected through the valve, the balloon unfolds from the silicone body, enabling the start of its inflation (2).



When fully inflated, the balloon, specific to MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy and designed to fit the anatomy of the gastric antrum, obtains its final shape with an air or saline solution volume of 10 to 50cc (3).

This step allows for calibration of the residual gastric antrum volume: the balloon is deflated and the stomach is then stapled and dissected following the position of the tube.

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1.3 Intended performance

The targeted performance levels are the following:

- MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy is indicated allows an intubation through the patient's mouth and down towards the stomach,
- MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy allows simpler calibration of the gastric pouch to be preserved during sleeve gastrectomy procedure as compared to the typical method of calibration (i.e., use of a nasogastric tube) by the surgeon.
- The dimension of the preserved gastric pouch obtained after using MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy optimizes sleeve gastrectomy effectiveness (weight loss and quality of life),
- MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy allows combination with a suction system in order to drain gastric fluids and/or to perform a leak test after the stapling step.

2. Predicate Device Comparison Summary

2.1 Table of comparison

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	Proposed device	Predicate devices	
Device Proprietary Name	MIDSLEEVE™, Calibration Tube for Sleeve Gatsrectomy	REALIZE™ Gastric Calibration Tube	Boehringer Laboratories Gastric Sizing Tube
510(k) Number	K142548	K 071764	K 130483
Device Common Name	Gastrointestinal Tube and Accessories	Gastrointestinal tubes	Gastrointestinal Tube and Accessories
Device Classification Name	Tubes, Gastrointestinal (and Accessories)	Tubes, Gastrointestinal (and Accessories)	Tubes, Gastrointestinal (and Accessories)
Manufacturer	Medical Innovation Développement	Obtech Medical SARL	Boehringer Laboratories, LLC
Product Code	KNT	KNT	KNT
FDA Regulation Number	21 CFR 876.5980	21 CFR 876.5980	21 CFR 876.5980
Device Classification	Class II 510(k) Premarket Notification	Class II 510(k) Premarket Notification	Class II 510(k) Premarket Notification
Review Advisory Comittee	Gastroenterology/ Urology	Gastroenterology/ Urology	Gastroenterology/ Urology
Intended Use			
Indications for Use Statement	MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy isindicated for use in the bariatric procedure known as Longitudinal Sleeve Gastrectomy (LSG), to drain & remove gastric fluid and to provide a calibration of the gastric pouch.	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 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 tube.
Typical Use	Sleeve gastrectomy procedures	Gastric and bariatric procedures	Gastric and bariatric procedures
Patient Population	Individuals undergoing Longitudinal Sleeve Gastrectomy procedure	Individuals undergoing bariatric and/or gastric procedures	Individuals undergoing bariatric and/or gastric procedures
Functions	Suction, drainage, sizing, irrigation	Suction, drainage, sizing, irrigation	Suction, drainage, sizing, irrigation
Environments of Use	Surgery Centers, Hospitals	Surgery Centers, Hospitals	Surgery Centers, Hospitals
Intraoperative Use	Yes	Yes	Yes
Design Characteristics			
Outer Diameter (French)	37.5Fr	38Fr	32Fr, 36Fr, or 40Fr
Length	900 mm	745 mm	760 mm
Tubing	Single lumen with rounded, open distal end	Single lumen with rounded, closed distal end	Single lumen with rounded, closed distal end
Distal side holes	Yes	Yes	Yes
Balloon and Inflation Valve	Yes	Yes	No
Balloon Position	Side of the distal end	6.8 cm from the distal end	NA
Markings	Every 5 cm, from 15 to 70 cm from the distal end of the tube	Markings are provided with the zero reference located approximately 39.6 cm from the proximal end of the balloon	Blue marking 30 – 40 – 50cm from the distal end of the tube
Materials			
Tubing Material	Silicone	Silicone	Styrene-Ethylene-Butylene-Styrene (SEBS Co-polymer)
Biological characteristics			
Sterility	Supplied sterile, disposable, single patient use	Supplied non-sterile, disposable, single patient use	Supplied non-sterile, disposable, single patient use

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2.2 Discussion

2.2.1 Intended use

The indications for use statement for the proposed device contain language that is not specifically incorporated in the indications for use statements of the predicate devices. The proposed device indications for use statement include "calibration". While the exact text "calibration" is not specifically included in the indications for use statements of the predicate devices, it refers to the terms "size", "sizing", "provide visible and tactile delineation of the stomach", and "size a gastric pouch".
The indications for use statement of the proposed device contain the text "Sleeve Gastrectomy" whereas it is not specifically stated in the indications for use statements of the predicate devices. It is included in the procedures referred to as "gastric and bariatric surgical procedures" in the indications for use statements of the predicate devices. The three devices are intended to perform the same functions: suction, drainage, sizing and irrigation.
The range of surgical applications and the patient population defined for the proposed device are not as wide as the ones defined for the predicate devices. However, all surgical applications for the MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy are within the range of surgical applications as defined by the predicate devices and do not affect the safety or performance of the device.

2.2.2 Technical Characteristics

Many similarities can be observed in the intended use of the three devices, including their main design characteristics and their general indications for use. However, differences concerning sterility, the tube and the balloon were identified.

Whereas the proposed device is supplied EO-sterilized, its predicate devices are supplied non-sterile. The proposed device is safer when it comes to infection risks and any additional risk of residual ethylene oxide intoxication is limited by the use of a validated aeration method (see section 14).

The tubes of the three devices differ slightly in their dimensions, materials and the features they include. As they allow the same calibration of a gastric pouch to be performed and do not make the tube handling more difficult, the differences of length and outer diameter do not impair the safety and performance of the device. Differences from the predicate devices which may exist concerning the materials used in the proposed device raise no safety concern since the biocompatibility of these materials was assessed (see section 15). Specificities concerning the features of the proposed device, such as the presence of a colored orientation band, the format and spatial distribution of the markings and the absence of suction connector do not impair its safety and performance and only improve the ease of use as compared to the predicate device.

The presence of a balloon on the proposed device allows calibration to be achieved. Its specific position on the tube does not impact this function as compared to the REALIZE™ Gastric Calibration Tube. No additional risk is implied and the main principles of operation of the device are not impacted.

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The differences discussed above do not affect the safety and effectiveness of the new device when used as labeled.

2.2.3 *Performance testing*

The MIDSLEEVE™, Calibration tube for Sleeve gastrectomy conforms to:

- ISO 11607-01:2009, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ISO 11607-01:2009, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
- ASTM F88-09:2009, *Standard test Method for Seal Strength of Flexible Barrier Materials*
- ASTM F1980-07:2011, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
- NF EN ISO 10993-1:2010 : *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- ASTM F1140/F1140M-13: *Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages*
- NF EN ISO 10993-5:2010: *Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity*
- NF EN ISO 10993-10: 2010: *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*

The MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy conforms engineering specifications for usability and reliability:

- Dimensional Analysis
- Reliability and Safety of the Distal Balloon Inflation and Proximal Valve
- Burst Volume Testing on the Inflated Balloon
- Distal End piece Gluing Reliability
- Valve to Tube Joint Strength Test
- Sterile Packaging Integrity

The performance testing conducted with the MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy referenced above indicates the new device performs equivalently to, or better than the predicate devices.

3. Conclusion

As evidenced from the similarities and the differences discussed above and from the intended use, technological characteristics and performance testing conducted, the MIDSLEEVE™, Calibration Tube for Sleeve Gastrectomy is as safe, as effective and performs as well as the predicate devices.