April 8, 2020

Standard Bariatrics
Alison Sathe
Regulatory
4362 Glendale Milford Rd.
Cincinnati, OH 45242

Re: K191885
Device Name: Standard Bougie
Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: March 9, 2020
Received: March 11, 2020

Dear Alison Sathe:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter, Jr.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191885

Device Name
Standard Bougie

Indications for Use *(Describe)*
The STANDARD BOUGIE® is indicated for use in conjunction with the STANDARD CLAMP® in vertical sleeve gastrectomy procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to serve as a sizing guide.

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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510(K) Summary

I. SUBMITTER

Standard Bariatrics
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Phone: 513-304-7971
Email: alison@standardbariatrics.com

Contact Person: Alison Sathe
Date Prepared: July 12, 2019

II. DEVICE

Name of Device: Standard Bougie
Common or Usual Name: Gastrointestinal tube and accessories
Classification Name: Tubes, Gastrointestinal (And Accessories) (21 CFR 876.5980)
Regulatory Class: II
Product Code: KNT

III. PREDICATE DEVICE

Predicate Device: Boehringer Laboratories Gastric Sizing Tube (Tradename: ViSiGi), K130483
Reference Device: Cook Incorporated Gastric Sizing Balloon Catheter, K173355

IV. DEVICE DESCRIPTION

The Standard Bougie is a single patient use, non-sterile device which consists of an 80 cm long, 18 French diameter tube with a luer connector at the proximal end of the tube. The tube has multiple holes and a rounded end. At the distal end is a balloon that can be inflated with water or saline to be used as a sizing guide.

The device is used to decompress the stomach, remove stomach contents, and allow for irrigation via the distal holes. The balloon is inflated and deflated as desired by connecting a syringe to the luer connector at the proximal end and injecting water into the balloon. The tube and balloon serve as a sizing guide.

V. INDICATIONS FOR USE

The STANDARD BOUGIE® is indicated for use in conjunction with the STANDARD CLAMP® in vertical sleeve gastrectomy procedures for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and to serve as a sizing guide.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Standard Bougie technological characteristics are provided in Table 1.

Table 1: Technological Characteristics

Product	Standard Bougie (subject device)	ViSiGi (Boehringer Laboratories Gastric Sizing Tube- K130483)	Equivalence
Typical Use	Gastric and bariatric surgical procedures	Gastric and bariatric surgical procedures	Same
Use Environment	Surgery centers, hospitals	Surgery centers, hospitals	Same
Patient Population	Patients undergoing bariatric and/or gastric procedures	Patients undergoing bariatric and/or gastric procedures	Same
Single Patient Use	Yes	Yes	Same
Sterility	Supplied non-sterile, single patient use only, disposable	Supplied non-sterile, single patient use only, disposable	Same
Functionality	Suction, drainage, irrigation and sizing	Suction, drainage, irrigation and sizing	Same
Method of Application	Insertion into the mouth and manually advance the distal end into the desired location within the stomach	Insertion into the mouth and manually advance the distal end into the desired location within the stomach	Same
Tubing Design	Double lumen with rounded, closed distal end	Single lumen with rounded, atraumatic distal end	Equivalent. The Standard Bougie double lumen is provided to allow for inflation of the balloon
Diameter	18 Fr	32 Fr, 36 Fr, or 40 Fr	Equivalent. The smaller size Standard Bougie is provided for surgeon preference as some prefer a smaller size lumen. 18Fr is a standard size for bougie devices and many are available in 18Fr.[1]
Length	95 cm	76 cm	Equivalent. The Standard Bougie is slightly longer than the ViSiGi. Both devices are long enough to perform their intended use. The Standard Bougie is slightly longer in order to ensure adequate length for the inflation lumen.
Materials	Thermoplastic elastomer	Styrene-Ethylene-Butylene-Styrene (SEBS Copolymer)	Equivalent. Both devices utilize materials compliant with ISO 10993 for their intended use. Both have similar mechanical properties to allow for their intended use.
Connection for suction	Yes	Yes	Same
Method of Suction	Connection with hospital suction, holes in distal end	Connection with hospital suction, holes in distal end	Same

[1] The Cook Gastric Sizing Balloon cleared pursuant to K173355 is 18Fr and is provided as an example of a currently marketed 18Fr diameter bougie.

	apply suction within the stomach	apply suction within the stomach	
Markings	Yes (numbers every 10 cm and gradations every 5 cm)	No	Equivalent. Markings are provided on the Standard Bougie to aid in device placement but are not necessary for the device use.
Packaging	Tyvek pouch for single device with 6 pouched devices within a cardboard box	Plastic pouch for a single device with 5 pouched devices within a cardboard box	Equivalent. Both devices are packaged nonsterile in a pouch with a cardboard outer package

VII. PERFORMANCE DATA

Standard Bougie performance testing has been submitted in this 510(k) as follows:

- Drainage Flow Rate Verification
- Balloon Strength Verification
- Balloon Size Verification
- Tensile Strength Verification
- Reliability Testing
- Device Usability

VIII. CONCLUSIONS

The Standard Bougie has the same intended use, and principles of operation as its predicate device. The minor differences in technological characteristics do not raise new questions of safety or effectiveness and testing demonstrates substantial equivalence. The Standard Bougie is substantially equivalent to the predicate device.