June 29, 2021

Standard Bariatrics
Michelle Schnell
Director of QA/ RA
4362 Glendale Milford Rd.
Cincinnati, OH 45242

Re: K210437
Trade/Device Name: Standard Bougie, SB38
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: May 28, 2021
Received: June 1, 2021

Dear Michelle Schnell:

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,

Je Hi An, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210437

Device Name
Standard Bougie, SB38

Indications for Use *(Describe)*
The STANDARD BOUGIE™ SB38 is indicated for use in conjunction with the Titan SGS ™ stapler in vertical sleeve gastrectomy pouch creation for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and insufflation, 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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STANDARD BARIATRICS™

510(K) Summary

I. SUBMITTER

Standard Bariatrics
4362 Glendale Milford Road
Cincinnati, OH 45242 USA

Phone: 513-702-6083
Email: michelle@standardbariatrics.com

Contact Person: Michelle Schnell
Date Prepared: June 24, 2021

II. DEVICE

Name of Device: Standard Bougie, SB38
Common or Usual Name: Gastrointestinal tube and accessories
Classification Name: Tube, Gastrointestinal (And Accessories) (21 CFR 876.5980)
Regulatory Class: II
Product Code: KNT

III. PREDICATE DEVICE

Standard Bariatrics, Standard Bougie (SB18), K191885

IV. DEVICE DESCRIPTION

The Standard Bougie SB38 is a single patient use, non-sterile device which consists of an 80 cm long, 38 French (38 Fr) 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 and insufflation 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™ SB38 is indicated for use in conjunction with the Titan SGS™ stapler in vertical sleeve gastrectomy pouch creation for the application of suction, stomach decompression, drainage of gastric fluids, irrigation and insufflation, and to serve as a sizing guide.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Standard Bougie SB38 technological characteristics are provided in Table 1.

STANDARD BARIATRICS™

Table 1: Technological Characteristics

Product	Standard Bougie, 38Fr (subject device)	Standard Bougie, 18Fr (predicate device, K191885)	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 requiring vertical sleeve gastrectomy	Patients undergoing bariatric and/or gastric procedures requiring vertical sleeve gastrectomy	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, insufflation, and sizing	Suction, drainage, irrigation, insufflation, 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	Double lumen with rounded, closed distal end	Same
Balloon Diameter Range	Minimum = 2.0 cm Nominal = 2.5 cm Maximum = 3.0 cm Length of balloon is approximately 4 cm long	Minimum = 1.5 cm Nominal = 2.0 cm Maximum = 2.5 cm Length of balloon is approximately 4 cm long	Equivalent. The SB18 is designed for use with the Standard Clamp, while the SB38 is not designed for use with the Standard Clamp. The larger balloon diameter ensures the same sizing in procedures not utilizing the Standard Clamp.
Catheter Diameter	38Fr	18Fr	Equivalent. The SB18 is designed for use with the Standard Clamp, while the SB38 is not designed for use with the Standard Clamp. The larger diameter ensures the same procedures not utilizing the Standard Clamp.
Overall Length	95 cm	95 cm	Same
Materials	Thermoplastic elastomer	Thermoplastic elastomer	Same
Connection for suction	Yes	Yes	Same
Method of Suction	Connection with hospital suction, holes in distal end apply suction within the stomach	Connection with hospital suction, holes in distal end apply suction within the stomach	Same
Markings	Yes (numbers every 10 cm and gradations every 5 cm)	Yes (numbers every 10 cm and gradations every 5 cm)	Same
Packaging	Tyvek pouch	Tyvek pouch	Same

VII. PERFORMANCE DATA

Standard Bougie SB38 performance testing has been submitted in this 510(k) as follows:

- Drainage Flow Rate Verification
- Balloon Strength Verification
- Balloon Size Verification
- Balloon Firmness Verification
- Tensile Strength Verification
- Reliability Testing

VIII. CONCLUSIONS

The Standard Bougie SB38 has the same intended use, and principles of operation as its predicate device. The conclusion drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device. The provision of the Standard Bougie in the 38 Fr size do not raise any new types of questions and the performance data provided reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.