October 31, 2022

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

Re: K222085
Trade/Device Name: Standard Tapered Bougie, 38 Fr (STB38)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: October 4, 2022
Received: October 5, 2022

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,

April Marrone, Ph.D., MBA
Acting Assistant Director
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)*
K222085

Device Name
Standard Tapered Bougie, 38Fr (STB38)

Indications for Use *(Describe)*
The Standard Tapered Bougie, 38Fr (STB38) 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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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: July 14, 2022

II. DEVICE

Name of Device: Standard Tapered Bougie, 38Fr (STB38)
Common or Usual Name: Gastrointestinal tube and accessories
Classification Name: Gastrointestinal tube and accessories
Regulation Number: 21 CFR 876.5980
Regulatory Class: II
Product Code: KNT

III. PREDICATE DEVICE

Name of Device: Standard Bariatrics, Standard Bougie, SB38
510(k) Number: K210437
Common or Usual Name: Gastrointestinal tube and accessories
Classification Name: Gastrointestinal tube and accessories
Regulation Number: 21 CFR 876.5980
Regulatory Class: II
Product Code: KNT

IV. DEVICE DESCRIPTION

The Standard Tapered Bougie, 38Fr (STB38) is a non-sterile, single patient use device. The device comprises a tube with a rounded tip featuring drainage holes, and a tapered balloon at the distal end. The proximal end of the Standard Tapered Bougie, 38Fr (STB38) includes a standard Luer lock valve for balloon inflation/deflation using the 60mL/CC syringe (provided) and a 7.5mm inner diameter straight tube for connection to operating room suction, Standard Bougie Hand Pump (SBHP) or tapered tip syringe.

V. INDICATIONS FOR USE

The Standard Tapered Bougie, 38Fr (STB38) 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 Tapered Bougie, 38Fr (STB38) technological characteristics are provided in Table 1.

Table 1: Technological Characteristics

Product	Standard Tapered Bougie, 38Fr (STB38, subject device)	Standard Bougie®, 38Fr (SB38, predicate device, K210437)	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
Method of Balloon Inflation	Connect a 60 ml syringe filled with air and inject into the balloon	Connect a 20 ml syringe filled with fluid and inject the desired amount of fluid into the balloon	Equivalent. Method of inflation is similar (air vs. liquid) and uses same type of connection via syringe.
Tubing Design	Double lumen with rounded, distal end	Double lumen with rounded, closed distal end	Equivalent. Both the subject and predicate device have the same double lumen tubing design. Both have a rounded, atraumatic tip with the same diameter and similar curvature. The subject device features drainage holes at the distal end, where the predicate device features drainage holes along the tubing.
Balloon Diameter Range	Maximum = 3.0 cm tapered to 38Fr (12.7mm) Diameter at angularis incisura: Minimum: 2.1 cm Nominal: 2.45 cm Maximum: 2.8 cm Length of balloon is approximately 16.6 cm long	Minimum = 2.0 cm Nominal = 2.5 cm Maximum = 3.0 cm Length of balloon is approximately 4 cm long	Equivalent. Both subject and predicate device are designed to ensure a minimum diameter at the angularis incisura. The additional length of the subject device aids in positioning down to the antrum to allow for stapler

			to be placed adjacent along length.
Catheter Diameter	38Fr	38Fr	Same
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, hole in distal end apply suction within the stomach	Connection with hospital suction, holes in distal end and along catheter apply suction within the stomach	Equivalent-Both devices have drainage ports that meet drainage flow rate requirements
Markings	Yes (numbers every 10 cm and graduations every 5 cm)	Yes (numbers every 10 cm and graduations every 5 cm)	Same
Packaging	HIPS Tray with PETG lid	Tyvek pouch	Equivalent. Both devices are provided non-sterile in packaging to protect during transport and storage. A tray was selected for the subject device to accommodate product configuration and to include a 60mL/CC syringe.
Accessories (SBHP)	Compatible with optional SBHP	Compatible with optional SBHP	Same

VII. PERFORMANCE DATA

Standard Tapered Bougie, 38Fr (STB38) performance testing was completed and provided in support of substantial equivalence within this 510(k) submission, as follows:

- Dimensional Verification: Balloon Length, Balloon Size, Shape and Firmness Verification
- Drainage Flow Rate Verification
- Tensile Strength Verification;
- Reliability Testing: demonstrating product meets functional requirements under simulated use conditions
- Aging and Transit Testing
- Balloon Strength
- Pressure Decay Testing: demonstrating device inflation using the Standard Bougie Hand Pump
- Biocompatibility Testing: Cytotoxicity, Sensitization, and Irritation

VIII. CONCLUSIONS

The Standard Tapered Bougie, 38Fr (STB38) has the same intended use, and principles of operation as its predicate device. The provision of the Standard Tapered Bougie, 38Fr (STB38) does not raise any new types of questions and the performance data provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.