September 23, 2021

Standard Bariatrics
Michelle Schnell
Director, Regulatory and Quality
4362 Glendale Milford Rd.
Cincinnati, OH 45242

Re: K212728
Trade/Device Name: Standard Bougie, 38 Fr. and Hand Pump
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: August 25, 2021
Received: August 27, 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,

for
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)*
K212728

Device Name
Standard Bougie, 38 Fr. and Hand Pump

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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510(k) Summary

I. Submitter's Information

Company Name:	Standard Bariatrics, Inc.
Address:	4362 Glendale Milford Road Cincinnati, OH 45242
Phone Number:	513-658-0328
Fax Number:	513-436-0201
Contact Person:	Michelle Schnell
Phone Number:	513-702-6083
Email Address:	michelle@standardbariatrics.com

Date Prepared: August 25, 2021

II. Device Information

Device Name: Standard Bougie (SB38) with Standard Bougie Hand Pump
Common Name: Bougie with Hand Pump Accessory
Regulation Description: Gastrointestinal tube and accessories
Regulatory Class: Class II
Regulation: 21 CFR 876.5980
Product Code: KNT

III. Predicate Device:

Standard Bougie (SB38), K210437, 21CFR 876.5980, Class II, Product Code KNT
Standard Bariatrics

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.

The Standard Bougie Hand Pump (SBHP) is an accessory to the current Standard Bougie (SB38). The SBHP is provided to enable insufflation of the stomach to enable controlled rearrangement of the gastric folds/rugae of the stomach or to perform leak testing during gastric and bariatric procedures.

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. Intended Use

Intended for use in vertical sleeve gastrectomy pouch creation during gastric and bariatric surgeries.

VII. Technological Characteristics

The technological specifications of Standard Bougie Hand Pump and its predicate have been evaluated to determine equivalence. As detailed in Section 010 of this Special 510(k) submission, upon reviewing and comparing intended use, design, materials, principle of operation and overall technological characteristics, the Standard Bougie Hand Pump is determined by Standard Bariatrics to be substantially equivalent to existing legally marketed devices (Table 1).

Table 1: Overview of Substantial Equivalence

	Subject Device (SB38 with Hand Pump Accessory)	**Predicate Device (SB38)**	**Determination**
Product Name	Standard Bougie, 38 Fr with Standard Bougie Hand Pump	Standard Bougie, 38 Fr	N/A
510(k) Holder	Standard Bariatrics	Standard Bariatrics	N/A
510(k) Number	TBD	K210437	N/A
Product Code	KNT	KNT	Same
Regulation	21 CFR 876.5980 Gastrointestinal tube and accessories	21 CFR 876.5980 Gastrointestinal tube and accessories	Same
Classification	II	II	Same
Intended 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	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,	Same

	Subject Device (SB38 with Hand Pump Accessory)	Predicate Device (SB38)	Determination
	insufflation, and to serve as a sizing guide.	and to serve as a sizing guide.	
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.	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.	Same
How Supplied	Single patient use, non-sterile device	Single patient use, non-sterile device	Same
Design Information			
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 Insufflation	Syringe OR Standard Bougie Hand Pump to apply air	Syringe to apply air	Equivalent insufflation pressure as compared with predicate device, Standard Bougie (SB38). Both devices are capable of connection with hospital air and suction. The addition of the Standard Bougie Hand Pump to the Standard Bougie includes the option for manual insufflation using a squeeze bulb.
Catheter Diameter	38Fr	38Fr	Same
Connection for suction	Yes	Yes	Same

	Subject Device (SB38 with Hand Pump Accessory)	Predicate Device (SB38)	Determination
Packaging	SB38: Tyvek Pouch Hand Pump Accessory: Polybag	SB38: Tyvek pouch	SB38 packaging remains unchanged. Hand pump accessory provided in Non-sterile packaging, routinely used for non-sterile products.

VIII. Performance Data

The data collected during the preparation of this submission was based upon the findings of the Risk Assessment for the addition of the Standard Bougie Hand Pump (SBHP) to the Standard Bougie (SB38). No changes other than the addition of the hand pump were made to the Standard Bougie (SB38) therefore, testing was provided in the original 510(k), K210437, remains applicable to the SB38 device.

In accordance with Standard Bariatrics' risk management procedures, design inputs were identified, risks evaluated, risk control measures implemented, and residual risk assessed. The risk analysis identified verification and validation activities as follows, which were conducted for the SBHP to confirm that no additional harms were introduced and the risk benefit analysis remains acceptable:

- Transit and 1 yr Accelerated Aging
- Performance Testing post Transit and 1 yr Accelerated Aging
- Pressure Decay Testing
- Insufflation Testing
- Reliability Testing

IX. Conclusion

The Standard Bougie (SB38) with Standard Bougie Hand Pump 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 addition of the Standard Bougie Hand Pump to the Standard Bougie SB38 in the 38 Fr size does not raise any new types of questions and the performance data provide reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.