May 18, 2022

Tools for Surgery, LLC
Arnold Leiboff, M.D.
President
8 Technology Drive, #100
East Setauket, NY 11773-3327

Re: K220218
Trade/Device Name: Siren SGT
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: April 12, 2022
Received: April 19, 2022

Dear Arnold Leiboff:

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.
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)*
K220218

Device Name
SIREN SGT™

Indications for Use *(Describe)*
The SIREN SGT™ is indicated for use in gastric and bariatric surgical procedures for gastric aspiration and lavage, and to assist in gastric sleeve formation by decompressing and stabilizing the stomach, and by serving 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.

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510(k) Summary

Submitter Name: Tools for Surgery, LLC
Submission Date: January 24, 2022
Submitter Address: 8 Technology Drive, #100
East Setauket, NY 11733-3327

Contact Person: Arnold R. Leiboff, M.D., President
Contact Email: aleiboff@toolsforsurgery.com
Phone Number: (631) 444-4448
Fax Number: (631) 444-5330

Prepared By: Arnold R. Leiboff, MD
Date Prepared: January 19, 2022

Device Trade Name: SIREN SGT™
Device Common Name: Gastrointestinal Tube and Accessories
Device Product Code: KNT
Regulation: 876.5980
Device Class: Class II
Classification Panel: Gastroenterology and Urology
Classification Name: Gastrointestinal Tube and Accessories

Predicate Device: Boehringer Laboratories Gastric Sizing Tube (ViSiGi 3D®)
510(k) Number: K130483

Device Description: The Tools for Surgery™ SIREN SGT™ gastric tube is a clean, non-sterile, single patient use device, comprising a 36 Fr insertion tube portion 109 cm long, a hub containing a suction regulating valve, an extension tube, pinch clamp, and connector. Tubular portions including the hub are flexible polyvinylchloride (PVC). There are multiple apertures in proximity to a rounded distal tip. Line and numeric markings are provided to indicate depth of insertion. The suction regulating valve limits negative pressure applied to the stomach to less than 175 mmHg, and produces an audible signal when the suction pressure in the stomach exceeds ≈160 mmHg.

Indications for Use: The SIREN SGT™ is indicated for use in gastric and bariatric surgical procedures for gastric aspiration and lavage, and to assist in gastric sleeve formation by decompressing and stabilizing the stomach, and by serving as a sizing guide.

Substantial Equivalence Comparison

Table 1

Device	*Proposed Device* SIREN SGT™	*Predicate Device* ViSiGi 3D®	Comparison
Manufacturer	Tools for Surgery, LLC	Boehringer Laboratories, LLC	
Model (Catalog No.)	SGT-36	5236	
Intended Use			
Indication for Use Statement	The Tools for Surgery™ SIREN SGT™ is indicated for use in gastric and bariatric surgical procedures for gastric aspiration and lavage, and to assist in gastric sleeve formation by decompressing and stabilizing the stomach, and by serving as a sizing guide.	The Boehringer Laboratories ViSiGi 3D® 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 guide.	Same
Typical Use	Gastric and bariatric procedures	Gastric and bariatric procedures	Same
Environments of Use	Surgery centers, hospitals	Surgery centers, hospitals	Same
Patient Population	Individuals undergoing bariatric and/or gastric procedures	Individuals undergoing bariatric and/or gastric procedures	Same
Intraoperative Use	Yes	Yes	Same
Functions	Suction, decompression, drainage, irrigation, sizing	Suction, decompression, drainage, irrigation, sizing	Same
Technical/Performance Characteristics			
Insertion Tube	Single lumen with rounded, closed distal end	Single lumen with rounded, closed distal end	Same
Insertion Tube Length	109 cm	107 cm	Same
Outer Diameter	36 Fr	36 Fr	Same
Distal Side Holes	18 or 36 apertures	108 apertures	Different
Internal Support of Distal Portion	No	Stainless steel coil	Different
Connector for Suction	Yes	Yes	Same
Suction Regulating Valve	Pressure relief valve	Inline shut-off valve	Different
Valve Actuating Pressure (Manufacture's specification)	129 mmHg ± 26 mmHg	125 mmHg ± 25 mmHg	Similar
Audible Pressure Signal	Yes	No	Different
Manual Suction Valve	Pinch Clamp	Selection (Slide) Valve	Different
Insertion Tube Material	DEHP-free PVC	SEBS Co-polymer	Different
Line Markings to Guide Insertion Depth	Yes	Yes	Same
Numeric Markings to Guide Insertion Depth	Yes	No	Different
Sterility	Supplied non-sterile	Supplied non-sterile	Same
Single Use, Disposable	Yes	Yes	Same

Performance/Non-Clinical Testing
The following non-clinical test reports have been submitted, referred to, and relied on in this 510(k) submission:

- VALVE FUNCTION TEST
- MAXIMAL NEGATIVE PRESSURE TEST
- AUDIBLE SIGNAL TEST
- VISIGI PRESSURE COMPARISONS
- DIMENSIONAL ANALYSIS TEST
- INSERTION TUBE KINK TESTS
- INSERTION TUBE COMPRESSION TESTS
- INSERTION TUBE STIFFNESS TEST
- JOINT STRENGTH TEST
- CAP BOND STRENGTH TEST
- CONNECTOR TEST
- SEAL TEST
- BUBBLE TEST, SGT
- BUBBLE TEST, VISIGI
- PACKAGE INSPECTION TEST
- COLOR TEXTURE PRINT TEST, AGED
- VALVE FUNTION TEST, AGED
- MAXIMAL NEGATIVE PRESSURE TEST, AGED
- TUBE DEGRADATION TEST, AGED
- INSERTION TUBE KINK TEST, AGED
- PINCH CLAMP FUNCTION TEST, AGED
- JOINT STRENGTH TEST, AGED
- CAP BOND STRENGTH TEST, AGED
- THE L929 NEUTRAL RED UPTAKE TEST (1 CONCENTRATION) – ISO
- THE INTRACUTANEOUS INJECTION TEST – ISO
- THE KLINGMAN MAXIMIZATION TEST – ISO

Discussion
The Tools for Surgery™ SIREN SGT™ gastric tube is similar to the predicate device Boehringer Laboratories Gastric Sizing Tube (ViSiGi 3D®).

Intended Use
The indications for use of the Tools for Surgery™ SIREN SGT™ and the Boehringer Laboratories ViSiGi 3D® are the same.

Technical Characteristics
The Tools for Surgery™ SIREN SGT™ gastric tube has technical characteristics similar to that of the predicate device. Both devices are orogastric tubes comprised of biocompatible elastomeric materials. The predicate device incorporates a slide valve to interrupt suction, while

the SIREN SGT™ employs a pinch clamp for this purpose. The insertion tubes of both devices have interval markings to help the surgeon and anesthesiologist gauge the depth of insertion and the position of the tip of the tube. The markings on the predicate device are simple lines that are indistinguishable from one another, while the markings on the SIREN SGT™ include numeric figures that indicate the exact distance to the forward tip of the insertion tube. The predicate device includes an internal metal coil support to stiffen the distal portion of its insertion tube; the SIREN SGT™ does not. The SIREN SGT™ insertion tube comprises one or two rows of 18 apertures, whereas the predicate device, ViSiGi 3D®, comprises six rows of 18 apertures. Both the SIREN SGT™ and predicate device connect to a vacuum source in order to deliver negative pressure to the gastric lumen. The suction pressure delivered by the vacuum source is adjustable by means of an external vacuum source suction regulator. Both the SIREN SGT™ and the predicate device incorporate integral suction regulating valves, which serve as additional means for limiting negative pressure applied to the gastric mucosa. The predicate device achieves this by means of an inline shut-off valve, which closes when negative pressure exceeds 100-150 mmHg. The SIREN SGT™ contains a pressure relief valve, which opens at 103 to 155 mmHg and limits the pressure in the insertion tube and stomach to negative 175 mmHg when full suction (≈360 mmHg) is applied. When negative pressure within the SIREN SGT™ insertion tube exceeds 160 mmHg an audible signal produced by mechanical means by the suction regulating valve informs the operator that excessive suction is being applied to the tube, and prompts the operator to lower the suction pressure by manually adjusting the vacuum source suction regulator.

Performance Testing

The performance tests referenced above substantiate that the proposed device performs equivalently to the predicate device, and validate the function of the suction regulating valve and audible signal mechanism.

Conclusion

As evidenced by the intended use, technical characteristics, and performance testing, the Tools for Surgery™ SIREN SGT™ gastric tube is substantially equivalent to the predicate device.