January 10, 2025

Tools for Surgery, LLC
Arnold Leiboff
President
8 Technology Drive, #100
East Setauket, New York 11733

Re: K242901
Trade/Device Name: ZZIREN™ Orogastric Tube; ZZIREN™ SGT Orogastric Tube - 32 Fr (ZZ-SGT-32); ZZIREN™ SGT Orogastric Tube - 36 Fr (ZZ-SGT-36); ZZIREN™ SGT Orogastric Tube - 40 Fr (ZZ-SGT-40); ZZIREN™ GBT Orogastric Tube - 32 Fr (ZZ-GBT-32); ZZIREN™ GBT Orogastric Tube - 36 Fr (ZZ-GBT-36); ZZIREN™ GBT Orogastric Tube - 40 Fr (ZZ-GBT-40)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: September 23, 2024
Received: December 11, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Anthony Lee -S

Anthony Lee, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242901

Device Name

ZZIREN™ Orogastric Tube;
ZZIREN™ SGT Orogastric Tube - 32 Fr (ZZ-SGT-32);
ZZIREN™ SGT Orogastric Tube - 36 Fr (ZZ-SGT-36);
ZZIREN™ SGT Orogastric Tube - 40 Fr (ZZ-SGT-40);
ZZIREN™ GBT Orogastric Tube - 32 Fr (ZZ-GBT-32);
ZZIREN™ GBT Orogastric Tube - 36 Fr (ZZ-GBT-36);
ZZIREN™ GBT Orogastric Tube - 40 Fr (ZZ-GBT-40)

Indications for Use *(Describe)*

The ZZIREN™ Orogastric Tube is indicated for use in gastric and bariatric surgical procedures for gastric aspiration and lavage, to serve as a size guide, and to test for leaks.

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) #: K242901

510(k) Summary

Prepared on: 2025-01-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Tools for Surgery, LLC
Applicant Address	8 Technology Drive, #100 East Setauket NY 11733 United States
Applicant Contact Telephone	(631)745-2179
Applicant Contact	Dr. Arnold Leiboff
Applicant Contact Email	aleiboff@toolsforsurgery.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ZZIREN™ Orogastric Tube; ZZIREN™ SGT Orogastric Tube - 32 Fr (ZZ-SGT-32); ZZIREN™ SGT Orogastric Tube - 36 Fr (ZZ-SGT-36); ZZIREN™ SGT Orogastric Tube - 40 Fr (ZZ-SGT-40); ZZIREN™ GBT Orogastric Tube - 32 Fr (ZZ-GBT-32); ZZIREN™ GBT Orogastric Tube - 36 Fr (ZZ-GBT-36); ZZIREN™ GBT Orogastric Tube - 40 Fr (ZZ-GBT-40)
Common Name	Gastrointestinal tube and accessories
Classification Name	Tubes, Gastrointestinal (And Accessories)
Regulation Number	876.5980
Product Code(s)	KNT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220218	SIREN SGT ™	KNT
K234145	Boehringer Laboratories ViSiGi® 3D	KNT

Device Description Summary

21 CFR 807.92(a)(4)

The ZZIREN™ Orogastric Tube is a non-sterile, single use device comprising a 37-inch-long insertion tube, a Y extension containing a suction regulating valve, and a pinch clamp. An accessory straight connector is included. The insertion tube and Y extension is made of flexible polyvinylchloride (PVC). The suction regulating valve limits negative pressure applied to the stomach or intestine to less than 175 mmHg, produces an audible signal when the suction pressure exceeds ≈160 mmHg, and is identical in all models. All six models have multiple apertures in proximity to a rounded distal tip. Three of the models, ZZ-SGT-32, ZZ-SGT-36, ZZ-SGT-40 have side-holes extending 13 cm from the tip, and three models, ZZ-GBT-32, ZZ-GBT-36, and ZZ-GBT-40, have side-holes extending 6 cm from the tip. The insertion tubes have diameters of 32, 36, and 40 Fr and have linear and numeric markings to indicate depth of insertion.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ZZIREN™ Orogastric Tube is indicated for use in gastric and bariatric surgical procedures for gastric aspiration and lavage, to serve as a size guide, and to test for leaks.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The ZZIREN™ Orogastric Tube is indicated for use in gastric and bariatric surgical procedures for gastric aspiration and lavage, to serve as a sizing guide, and to test for leaks. The Inclusion of "to test for leaks" for ZZIREN™ Orogastric Tube differs from the indication stated for the primary predicate device in Submission K220218. "To test for leaks" is included in the indications for use of the secondary reference ViSiGi® 3D, which was cleared per Special 510(k) K234145. Use of ZZIREN™ Orogastric Tube for leak testing allows the surgeon to more efficiently assess staple line integrity intraoperatively and does not impact the procedures overall safety and effectiveness or the intended use of the device to assist in completion of gastric and bariatric surgery.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed Tools for Surgery™ ZZIREN™ Orogastric Tubes, models ZZ-SGT-32, ZZ-SGT-36, ZZ-SGT-40, ZZ-GBT-32, ZZ-GBT-36, and ZZ-GBT-40 have technical characteristics similar to that of the primary predicate device, Tools for Surgery™ SIREN SGT™ gastrointestinal tube. All devices are orogastric tubes comprised of biocompatible elastomeric materials.

The proposed devices differ from the predicate device, SIREN SGT™ model SGT-36, by having a Y extension in place of three separate parts (Y connector, extension tube, and suction connector), by having the additional insertion tube calibers of 32 and 40 Fr, and by having 32, 48, 72, or 108 distal apertures (side-holes) instead of the 18 or 36 distal apertures specified in the predicate's 510(k) submission (K220218). (The ViSiGi 3D® model 5236 [510(k) no. K130483], the antecedent predicate device for K220218, has 108 side holes.)

The Y extension is a single, integral, molded unit having a forward stem to join with the insertion tube, a first arm to contain the suction regulating valve, and a second arm having a segment around which the pinch clamp is disposed, and a rearward expansion to receive a straight connector accessory that is attachable to medical suction tubing. All proposed models have similar Y extensions but different insertion tube calibers or number of apertures. All models employ the same pinch clamp as the primary predicate device to interrupt suction. All models, proposed and predicate, have identical index markings to help the surgeon and anesthesiologist gauge the depth of insertion and the position of the tube within the upper gastrointestinal tract.

All models, proposed and predicate, 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. All models, proposed and primary predicate, incorporate an identical integral suction regulating valve, which serves as additional means for limiting negative pressure applied to the gastric mucosa. This is a pressure relief valve, which opens at 103 to 155 mm Hg and limits the pressure in the insertion tube and stomach to less than negative 175 mm Hg when full suction (≈360 mm Hg) is applied. When negative pressure within the insertion tube of any model, proposed or primary predicate, exceeds 160 mm Hg an audible signal produced by mechanical means by the suction regulating valve informs the operator that excessive suction is being applied, and prompts the operator to lower the suction pressure by manually adjusting the vacuum source suction regulator.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The stiffness, compressibility, and propensity to kink of the insertion tubes of the proposed device are compared to the those the primary and secondary predicates. The pinch clamp function of the proposed device is compared to the function of the same part on the primary predicate. Accessory tubing connectors are shown to fit and function well. The proposed device is shown to be compatible with a device for leak testing.

The INSERTION TUBE KINK TEST data shows that the six models of the proposed ZZIREN™Orogastric Tube are substantially equivalent in their propensity to kink to the predicate SIREN SGT™ and are therefore as unlikely to interfere with gastric decompression, lavage, and stapling. The INSERTION TUBE STIFFNESS TEST shows that all models of the proposed device are equally or less stiff than the insertion tubes of their corresponding predicate device and are therefore equally or less likely to cause visceral injury. The INSERTION TUBE COMPRESSION TEST shows that all models of the proposed device are equally or less likely to be inadvertently stapled during gastric surgery than the corresponding predicate device. The PINCH CLAMP TEST shows that the performance of the PINCH CLAMP on the proposed ZZIREN™ Orogastric Tube is substantially equivalent to its performance on the predicate SIREN SGT™. The CONNECTOR TESTS show that both accessory straight tubing connectors attach to the proposed device easily and reversibly in a secure manner and provide a reliable connection to medical suction tubing. The AIR SYRINGE COMPATIBILITY TEST shows that the proposed device and the Bariatric Air Syringe are compatible and may be safely used together for leak testing. Dimensional Analysis Tests of all models of the proposed ZZIREN™ device show that all models are made to design specifications.