February 15, 2023

ReShape Lifesciences
Dov Gal
VP of Regulatory, Quality, & Clinical
1001 Calle Amanecer
San Clemente, CA 92673

Re: K230131
Trade/Device Name: ReShape Calibration Tubes
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: January 16, 2023
Received: January 17, 2023

Dear Dov Gal:

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 An -S

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)*

K230131

Device Name
ReShape Calibration Tubes™

Indications for Use *(Describe)*

ReShape Calibration Tubes™ are indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid, irrigate, and act 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

I. Basic Information

510(k) Owner	ReShape Lifesciences 1001 Calle Amanecer San Clemente CA 92673 Phone: (844) 937-7374 Establishment Registration No: 3013508647
Contact Person	Dov Gal, VP of Regulatory, Quality, & Clinical
Date of summary	January 16, 2023
Trade Name	The ReShape Calibration Tubes™
Common Name	Introduction/Drainage Catheter
Classification	Class II, KNT
Classification Name	Gastrointestinal Tube and Accessories
Predicate Device	ReShape Lifesciences Gastrointestinal Boundary Identifier (GIBI HD ™) Calibration Tube, K221898

II. DEVICE DESCRIPTION

The subject device is the same as the Gastrointestinal Boundary Identifier (GIBI HD ™) Calibration Tube, which is also manufactured by our company, ReShape Lifesciences Inc., and was cleared under 510(k) K221898. The reason for the submission is the addition of a contraindication to the Directions for Use (DFU). Other changes described in this submission are the device name and minor edits to the DFU.

The ReShape Calibration Tubes™ is a flexible gastric tube designed to be used in gastric and bariatric surgical procedures and is available in three larger sizes. The trade name has been changed Gastrointestinal Boundary Identifier (GIBI HD ™) to ReShape Calibration Tubes ™ for these three (3) sizes.

The ReShape Calibration Tubes™ provide visible and tactile delineation of the gastroesophageal (GE) junction, and its location relative to the esophageal hiatus and antrum of the stomach. The device provides the ability to decompress the stomach, drain and remove gastric fluid and act as a sizing guide (**Figure 1**).

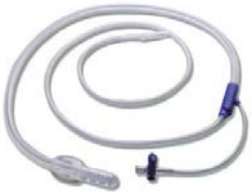

Figure 1: ReShape Calibration Tubes™ (Representative figure of all Models: B-2032, B-2036, B-2040)

III. INDICATIONS FOR USE

ReShape Calibration Tubes™ are indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid, irrigate, and act as a sizing guide.

IV. BASIS FOR SUBSTANTIAL EQUIVALENCE

Substantial equivalence of the ReShape Calibration Tubes™ to the predicate device (ReShape Lifesciences Gastrointestinal Boundary Identifier (GIBI HD ™) Calibration Tube, K221898) was already established through an evaluation of the indications for use, principle of operation, device design, materials of construction, and an assessment of usability, safety, and effectiveness via bench studies.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the ReShape Calibration Tubes and the predicate device is provided in **Table 1**.

Table 1: Comparison of Subject Device and Predicate Device

Feature	Predicate Device ReShape Lifesciences Gastrointestinal Boundary Identifier (GIBI HD ™) Calibration Tube, K221898	Subject Device ReShape Calibration Tubes	Effect on Substantial Equivalence
Product Code	KNT	Same	None
Regulatory Class	Class II	Same	None
Regulation Number	21 C.F.R. 876.5980	Same	None
Regulation Name	Gastroenterology-Urology	Same	None

Feature	Predicate Device ReShape Lifesciences Gastrointestinal Boundary Identifier (GIBI HD ™) Calibration Tube, K221898	Subject Device ReShape Calibration Tubes	Effect on Substantial Equivalence
Indications for Use	The GIBI HD™ is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid, irrigate, and act as a sizing guide.	ReShape Calibration Tubes™ are indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid, irrigate, and act as a sizing guide.	None
Outer Diameter / French Size nominal	**B-2032**: 32F **B-2036:** 36F**B-2040**: 40F	Same	None
Outer Diameter / French Size distal tip	**B-2032**: 38F **B-2036:** 42F **B-2040**: 42F	Same	None
Outer Diameter / French Size deflated balloon	**B-2032**: 50F **B-2036:** 52F**B-2040**: 56F	Same	None
Tubing	Dual lumen	Same	None
Distal Side Holes	3 aspiration holes proximal to the balloon to ensure a steady vacuum	Same	None
Distal Tip	Molded tip with twelve (12) aspiration eyelets.	Same	No impact to substantial equivalence.
Connector for Suction	The catheter includes an adapter for room suction	Same	None
Balloon + Inflation Valve	The balloon has an inflation capacity ≥ 100 cc min.	Same	None
Tubing Material	Silicone	Same	None
Markings	Indication marks at 30, 35, 40, 45, and 50, 55, and 60 centimeters.	Same	None
Sterility	Non-sterile, disposable, single patient use	Same	None
Shelf Life	2 years	Same	None.

VI. PERFORMANCE DATA

Bench testing was not conducted and remains same as the predicate device cleared under K221898.

VII. CONCLUSION

Data presented in this submission demonstrate that the updated DFU is similar and equivalent to of the ReShape Gastrointestinal Boundary Identifier (GIBI HD) Calibration tube (K221898).

The ReShape Calibration Tubes™ device, and the predicate device (Gastrointestinal Boundary Identifier (GIBI HD) Calibration tube):

- have the same intended use,
- use the same principle of operation,
- incorporate the same design,
- have the same construction and material, and
- are both provided non-sterile.

In summary, the ReShape Calibration Tubes™ device described in this submission is substantially equivalent to the predicate device, the Gastrointestinal Boundary Identifier (GIBI HD) Calibration tube (K221898).