May 16, 2024

ReShape Lifesciences
Eva Chang
Senior Director of Regulatory Affairs
18 Technology Drive
Suite 110
Irvine, California 92618

Re: K241039
Trade/Device Name: ReShape Calibration Tubes (B-2032, B-2036, B-2040);
ReShape Calibration Tubes (B-2017);
Gastric Balloon Suction Catheter (B-2020)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: April 16, 2024
Received: April 16, 2024

Dear Eva Chang:

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.

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 C. Lee, Ph.D., M.B.A.
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)*

K241039

Device Name

ReShape Calibration Tubes (B-2032, B-2036, B-2040);
ReShape Calibration Tubes (B-2017);
Gastric Balloon Suction Catheter (B-2020)

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.

The Gastric Balloon Suction Catheter 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared on: 2024-04-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ReShape Lifesciences
Applicant Address	18 Technology Drive Suite 110 Irvine CA 92618 United States
Applicant Contact Telephone	949-245-1174
Applicant Contact	Ms. Eva (Ming Yi) Chang
Applicant Contact Email	echang@reshapelifesci.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ReShape Calibration Tubes (B-2032, B-2036, B-2040); ReShape Calibration Tubes (B-2017); Gastric Balloon Suction Catheter (B-2020)
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
K220455	Lap-Band System Calibration Tube	KNT

Device Description Summary

21 CFR 807.92(a)(4)

The ReShape Calibration Tubes™ (Model B-2032, B-2036, B-2040, and B-2017) and the Gastric Balloon Suction Catheter (Model B-2020) are manufactured by our company, ReShape Lifesciences. These catheters are flexible gastric tubes designed to be used in gastric and bariatric surgical procedures. The catheters provide visible and tactile delineation of the gastroesophageal (GE) junction and its location relative to the esophageal hiatus and antrum of the stomach. These devices provide the ability to decompress the stomach, drain and remove gastric fluid, irrigate, and act as a sizing guide. Models B-2032, B-2036, and B-2040 were previously cleared under K230123. Model B-2017 was previously named Lap-Band System Calibration Tube and cleared under K220455. Model B-2020 was previously cleared under K002838. There are no changes to the principle of operation or technological characteristics of the devices.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

The Gastric Balloon Suction Catheter 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject devices have the same intended use as the predicate device. The minor edits to the indications for use statement do not alter the indications or intended use .

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices, ReShape Calibration Tubes (Models B-2017, B-2032, B-2036, B-2040) and the Gastric Balloon Suction Catheter (Model B-2020), are substantially equivalent to the predicate device Lap-Band System Calibration Tube (Model B-2017) cleared to market June 7, 2022 (K220455), with respect to the indications for use, condition of use, designs, and fundamental technological and performance characteristics. The minor differences between the subject devices and the predicate devices include the material change to the black length marking ink/paste printed on the outer shaft of the catheters. Other minor labeling updates include product name change, the addition of a general contraindication, and labeled shelf life, which have no impact on the substantial equivalence.

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

The final finished subject devices with the proposed design modification have been tested in accordance with applicable ISO 10993 standards and in compliance with 21 CFR Part 58, and concluded non-cytotoxic, non-sensitizing, and non-irritant. The labeled shelf life of 7 years is supported by leveraging the shelf life data of Model B-2017 previously cleared under K220455 with appropriate rationale. No bench testing, packaging study, usability study, or sterility are deemed applicable or necessary for these subject devices with proposed modifications.