July 28, 2022

ReShape Lifesciences
Michelle Ravert
Regulatory Affairs Manager
1001 Calle Amanecer
San Clemente, CA 92673

Re: K221898
Trade/Device Name: Gastrointestinal Boundary Identifier (GIBI HD™)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: June 28, 2022
Received: June 30, 2022

Dear Michelle Ravert:

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,

April Marrone, Ph.D., MBA
Assistant Director (acting)
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)*
K221898

Device Name
Gastrointestinal Boundary Identifier (GIBI HD™)

Indications for Use *(Describe)*
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.

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. Basic Information

510(k) Owner	ReShape Lifesciences 1001 Calle Amanecer San Clemente CA 92673 Phone: (844) 937-7374 Establishment Registration No: 3013508647
Contact Person	Michelle Ravert, Regulatory Affairs Manager
Date summary Prepared	July 26, 2022
Trade Name	Gastrointestinal Boundary Identifier (GIBI HD™)
Common Name	Introduction/Drainage Catheter
Classification name	Gastrointestinal tube and accessories (21 CFR 876.5980)
Regulatory Class	Class II
Product Code	KNT
Predicate Device	Lap-Band® System Calibration Tube, K220455
Reference Device	ViSiGi 3D®, K130483

II. DEVICE DESCRIPTION

The Gastrointestinal Boundary Identifier, or GIBI HD™, is a flexible gastric tube designed to be used in gastric and bariatric surgical procedures. The catheter provides visible and tactile delineation of the antrum of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid and size a gastric pouch.

The dual lumen GIBI HD utilizes one lumen for drainage, suction and irrigation and the second lumen to inflate/deflate the balloon. The catheter is attached to a 32-inch suction tubing and a 6-inch tubing with a stopcock for filling the balloon.

III. 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.

IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technical Element	GIBI HD B-2032, B-2036, B-2040	Predicate Device Calibration Tube, K220455
Outer Diameter (OD), inches	B-2032 = 0.420" + 0.000" / -0.012" B-2036 = 0.472" + 0.000" / -0.012" B-2040 = 0.525" + 0.000" / -0.012"	0.380" +0.000" / - 0.012"
OD, French Size	B-2032 = 32 F B-2036 = 36 F B-2040 = 40 F	29F
Working length (distal end of Y-connector to distal end of distal tip)	32.43 ± 0.52"	24.73" ± 0.52"
Tubing Material	Silicone	Silicone

V. PERFORMANCE DATA

Test Performed	Purpose	Acceptance Criteria	Results
Balloon leakage test	The balloon component of the GIBI HD shall inflate to a minimum volume of 100 cc without exhibiting fluid leak or air egress.	Samples retained 100 cc of fluid at least 1 minute without leakage.	Pass
Fluid removal test	The GIBI HD shall remove a minimum of 500 cc of saline or clean water in under 1 minute.	Samples evacuated a minimum of 500 cc of fluid in under 1 minute.	Pass
Balloon bond joint strength test	The mated joint between the GIBI HD 's Balloon and Tubing shall withstand a minimum of 13 lbf prior to separation.	Samples did not exhibit balloon separation under 13 lbf.	Pass
Distal tip bond joint strength test	The mated joint between the GIBI HD 's distal tip and Tubing shall withstand a minimum of 19.5 lbf prior to separation.	Samples did not exhibit sensor tip separation under 19.5 lbf.	Pass
Stopcock separation test	The stopcock component of the GIBI HD shall withstand a minimum of 1 lbf prior to separation from the fill tube.	Samples did not exhibit stopcock separation under 1 lbf.	Pass
Fill tube separation test	The fill tube attached to the stopcock of the GIBI HD shall withstand a minimum of 1 lbf prior to separation from the y connector.	Samples did not exhibit fill tube separation under 1 lbf.	Pass
Adapter tubing separation test	The proximal tubing of the GIBI HD shall withstand a minimum of 1 lbf prior to separation from the y connector.	Samples did not exhibit adapter tube separation under 1 lbf.	Pass
Adapter separation test	The adapter of the GIBI HD shall withstand a minimum of 1 lbf prior to separation from the adapter tube.	Samples did not exhibit adapter separation under 1 lbf.	Pass

Test Performed	**Purpose**	**Acceptance Criteria**	**Results**
Visual Inspection and Measurement verification test	The dual lumen catheter component of the GIBI HD, from the distal edge of the Y connector to the end of the dual lumen catheter, shall have a minimum length of 75 cm.	Minimum length of measured sample is 75 cm.	Pass
	The dual lumen catheter component of the GIBI HD shall include indication marks on the surface of the tube at 30, 35, 40, 45, 50, 55 and 60 cm with respect to the distal portion of the component.	Indicator marks are located 30, 35, 40, 45, 50, 55, and 60 cm with respect to distal portion of the component.	Pass
	The dual lumen catheter component of the GIBI HD shall have three size configurations: 0.42" (32 Fr), 0.47" (36 Fr) and 0.53" (40 Fr).	Outer diameter of 32Fr, 36Fr and 40Fr samples are 0.42'', 0.47'' and 0.53'', respectively.	Pass

VI. BASIS FOR SUBSTANTIAL EQUIVALENCE

Substantial equivalence of the GIBI HD to the predicate device (Lap-Band® System Calibration Tube, K220455) was 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.

The data presented in this summary demonstrates the technological similarity and equivalency of the GIBI HD to the predicate device (Lap-Band® System Calibration Tube, K220455).

The devices:

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

In addition, the GIBI HD and the reference device (ViSiGi 3D, K130483) have the same outer diameter sizes and are substantially equivalent with respect to working length.

In summary, the Gastrointestinal Boundary Identifier (GIBI HD™) device described in this submission is substantially equivalent to the predicate device, the LAP-BAND System Calibration tube (K220455).