April 10, 2025

Changzhou Xin Neng Yuan Medical Stapler Co., Ltd.
℅ Jenny Xia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K250389
Trade/Device Name: XNY Disposable Gastric Calibration Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: February 9, 2025
Received: February 11, 2025

Dear Jenny Xia:

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 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.

510(k) Number *(if known)*
K250389

Device Name
XNY Disposable Gastric Calibration Tube

Indications for Use *(Describe)*
XNY Disposable Gastric Calibration Tube is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.

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."

510k Summary
K250389

1. General Information

Applicant Information	Changzhou Xin Neng Yuan Medical Stapler Co., Ltd. No.51 Shuishan Rd, Zhonglou Economic Development District Changzhou, Jiangsu, China www.xnywhq.com whq@xnywhq.com
Contact Person	Jenny Xia LSI International Inc 504E Diamond Ave., Suite H Gaithersburg, MD 20877 jxia@lsi-consulting.org 301-525-6856
Date Summary Prepared	February 9, 2025
Device Common Name	Disposable Gastric Calibration Tubes
Device Trade Name	XNY Disposable Gastric Calibration Tubes
FDA Product Code	KNT
Classification Name	876.5980 Gastrointestinal tube and accessories
Classification	Class II
Predicate Device	Gastrointestinal Boundary Identifier (GIBI HD™), K221898

2. Device Description
The XNY Disposable Gastric Calibration Tubes are indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch. The device has the advantages of accurately determining residual gastric capacity and easy positioning, and it can be connected to a suction device to extract the gas or liquid in the patient's stomach.

3. Indication for Use
XNY Disposable Gastric Calibration Tube is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.

4. Comparison of Technological Characteristics with the Predicate Device

Feature	**Predicate Device Calibration Tube, K221898**	**Subject Device Calibration Tubes K250389**	**Effect on Substantial Equivalence**
Indications for Use	The GIBI HDTM 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.	Product is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.	None
Outer Diameter	B-2032: 10.5mm +0/-0.3mm	JZGA/B-32FR: 10.5mm±0.5mm	Outer diameters are similar and no impact to

	B-2036: 11.9mm +0/-0.3mm B-2040: 13.2mm +0/-0.3mm	JZGA/B-34FR: 11.2mm±0.5mm JZGA/B-36FR: 11.9mm±0.5mm JZGA/B-38FR: 12.5mm±0.5mm JZGA/B-40FR: 13.2mm±0.5mm JZGA/B-42FR: 13.9mm±0.5mm JZGA/B-44FR: 14.5mm±0.5mm	substantial equivalence
Working Length	823.7mm±13.2mm	JZGA type: 700mm±10mm JZGB type: 900mm±20mm	No impact to substantial equivalence with the similar lengths.
Tubing	Dual lumen	JZGA: Dual lumen JZGB: single lumen	Dual lumen and single lumen only choose different models according to different clinical needs, and no impact to substantial equivalence.
Distal Tip	Includes a tip distal to the balloon with 12 aspiration holes.	Includes a tip distal to the balloon with 3 aspiration holes.	The number of suction holes has no substantial effect on the actual use. No impact to substantial equivalence
Connector for Suction	The catheter includes an adapter for room suction	There is a matching adapter, which can be adapted to various connectors	None
Balloon + inflation Valve	The balloon has an inflation capacity ≥ 100 cc min. The catheter is attached to a 6- inch tubing with a stopcock for filling the balloon.	JZGA type balloon with inflation capacity ≥ 100cc/min. JZGB has no balloon	None
Tubing Material	Silicone	Medical grade silicone	None
Markings	Indication marks at 30, 35, 40, 45, and 50 centimeters.	A type indication marks at 52, 53, 54, 55, 56, 57, 58, 59, 60 centimeters; B type indication marks at 30, 31, 32, 33…89, 90 centimeters	Marks are included and no impact to Substantial equivalence
Connector	Luer taper, tape adapter	Normal joint, tape joint	Similar adapters and no impact to substantial equivalence
Sterility	Non-sterile, disposable, single patient use	Sterile, single-use, single patient use	None

5. Performance Data

Test Performed	Purpose	Acceptance Criteria	Results
Firmness of the balloon	The purpose of this test is to evaluate the firmness of the balloon of Disposable gastric calibration tube.	The firmness of the balloon is greater than 60N.	Pass
The firmness between the suction port and the catheter	The purpose of this test is to evaluate the firmness between the suction port and the catheter of Disposable gastric calibration tube.	The firmness between the suction port and the catheter is greater than 5N.	Pass
The catheter aspiration function	The purpose of this test is to evaluate catheter aspiration function of Disposable gastric calibration tube.	The catheter should be able to draw out 500ml of liquid within 1 minute.	Pass
The firmness between suction port 2 (adapter) and catheter	The purpose of this test is to evaluate the firmness between suction port 2 and catheter of Disposable gastric calibration tube.	The firmness between suction port 2 and catheter is greater than 30N.	Pass
The firmness of the inflation valve	The purpose of this test is to evaluate the firmness of the inflation valve of Disposable gastric calibration tube.	The firmness of the inflation valve is greater than 20N.	Pass
Balloon leakage test	The purpose of this test is to evaluate balloon leakage.	Can tolerate double the working pressure of 80 ml gas without leakage or damage.	Pass
Biocompatibility Testing	The purpose of this test is to evaluate the device to meet ISO 10993 on biocompatibility for Biological evaluation of medical devices.	No cytotoxicity No sensitization No irritation.	Pass
Balloon Inspection	The purpose of this test is to evaluate the appearance of the balloon of Disposable gastric calibration tube.	The balloon should be colorless and transparent. The balloon should be tightly connected to the tube and the connection between the balloon and the tube should be homogeneous and without twisting.	Pass
Tube Dimension	The purpose of this test is to evaluate the tube dimension of Disposable gastric calibration tube.	The tube length and diameter meet the required measurements.	Pass
Tube scale mark inspection	The purpose of this test is to evaluate the appearance of the tube scale marks on Disposable gastric calibration tube.	The scale marks on the tube should be clear and not faded.	Pass

Tube resistance to bend and break	The purpose of this test is to evaluate the Disposable gastric calibration tube's resistance to bending and breaking.	Hold the tube at both ends and bend the tube so that the 1cm of long tube at both ends are parallel and in contact, hold for 15 seconds, then release, ensuring that no creases form at the bend of the catheter.	Pass
Firmness of insertion tip and tube	The purpose of this test is to evaluate the firmness of the insertion tip and tube of Disposable gastric calibration tube.	The connection between the Insertion tip and the tube should be able to withstand a static axial pull of 15N for 15S without breaking or falling off.	Pass
The firmness between suction port 1(Adapter 1) and suction port 2(Adapter 2) is greater than 5N.	The purpose of this test is to evaluate the firmness between adapter 1 and adapter 2	The firmness between adapters is greater than 5N.	Pass
Pipe Clip Sealability Test.	The purpose of this test is to evaluate the Pipe Clip sealability of disposable gastric calibration tubes.	When the Pipe Clip is closed, no bubbles are generated at the catheter port.	Pass

6. Basis for Substantial Equivalence

Substantial equivalence of the XNY Disposable Gastric Calibration Tube to the predicate device was established through an evaluation of the indications for use, principle of operation, device design, materials of construction, and an assessment of safety, and effectiveness via bench studies.

The data presented in this summary demonstrates the technological similarity and equivalency of the XNY Disposable Gastric Calibration Tube to the predicate device (GIBI HD, K221898).

The devices:

- have the same intended use,
- use the same principle of operation,
- incorporate the same basic design,
- use similar construction and material

7. Conclusion

Based on the non-clinical assessments, the comparison of the device classification, indications for use, operating principle, technological characteristics, and biocompatibility that the subject device, the XNY Disposable Gastric Calibration Tube, is substantially equivalent to the predicate device, the GIBI HD, K221898. Any differences between the subject device and the predicate device do not raise different questions of safety and effectiveness.