July 26, 2022

Nasmed
% Joseph Azary
Advisor / Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, CT 06484

Re: K212407
Trade/Device Name: Gastric Lightguide (GLG)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: December 22, 2021
Received: December 23, 2021

Dear Joseph Azary:

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)*
K212407

Device Name
Gastric Lightguide (GLG)

Indications for Use *(Describe)*
Use in gastric and bariatric surgical procedures for the application of suction, stomach decompression and drainage of gastric fluids and irrigation.

Patient Population: For use in Adults only

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

Nasmed Gastric Lightguide (GLG)

Sponsor:

Nasmed
Ul Jana Nowaka Jezioranskiego 7/184
03-984 Warszawa
Poland

Regulatory Correspondent for 510(k):

Joseph Azary
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, CT 06484
Phone: 203-242-6670

Date Updated: July 22, 2022

Name of Device: Gastric Light Guide (GLG)

Common or Usual Name: Gastrointestinal tube and accessories

Classification Name: Gastrointestinal tube and accessories

Regulatory Class: Class II, 21 CFR 876.

Product Code: KNT

Predicate Device:

Primary Predicate: K130483, ViSiGi 3D

Reference Device:

Reference Device: K964561, Transillumination Lighted Bougie System

Device Description

The GLG (Gastric Light Guide) is a multi-channel bougie which allows all functions to be performed with one device and one insertion. The GLG is a single use device that is provided sterile (sterilized using Ethylene Oxide).

A light channel runs the full length of the bougie, illuminating the oral cavity and pharynx for proper insertion. The GLG connects to a battery powered light handle that are 510(k) exempt under product codes FSW and HJM.

The GLG transilluminates the anterior stomach wall while suction holds it in place, highlighting the shape of the bougie and allowing the surgeon to see the best path for stapling.

The GLG is inserted at the beginning of the procedure and not removed until after the leak test.

The GLG is composed of a double lumen tube composed of medical grade PVC with holes and an atraumatic tip.

There is a blue connector for use with standard suction equipment 36 Fr.

The light wire is a 3mm diameter wire composed of PMMA with several cut-outs. The light wire does not make patient contact.

There is a black connector 10 Fr for the light wire to be connected to a reusable light handle, battery operated LED light source.

There is only one model available GLG001, size 36 Fr and 1000mm in length with a closed lightwire channel.

The GLG devices are packaged in paper/film packages of material suitable for ethylene oxide sterilization. The units are sold in carton boxes which contain 6 intermediate boxes of 5 units of GLG each.

Intended Use / Indications for Use

Use in gastric and bariatric surgical procedures for the application of suction, stomach decompression, drainage of gastric fluids and irrigation.

Summary of Technological Characteristics

The subject device is The GLG (Gastric Light Guide) is a multi-channel bougie which allows all functions to be performed with one device and one insertion. The GLG is a single use device that is provided sterile (sterilized using Ethylene Oxide) validated per ISO 11135-1 affording a Sterility Assurance Level of 10^{-6}.

A light channel runs the full length of the bougie, illuminating the oral cavity and pharynx for proper insertion. The GLG connects to a battery powered light handle that are 510(k) exempt under product codes FSW and HJM.

The GLG transilluminates the anterior stomach wall while suction holds it in place, highlighting the shape of the bougie and allowing the surgeon to see the best path for stapling.

The GLG is inserted at the beginning of the procedure and not removed until after the leak test.

The GLG is composed of a double lumen tube composed of medical grade PVC with holes and an atraumatic tip.

There is a blue connector for use with standard suction equipment 36 Fr.

The light wire is a 3mm diameter wire composed of PMMA with several cut-outs. The light wire does not make patient contact.

There is a black connector 10 Fr for the light wire to be connected to a reusable light handle, battery operated LED light source.

There is only one model available GLG001, size 36 Fr and 1000mm in length with a closed lightwire channel.

Substantial Equivalence Comparison

The GLG Gastric Light Guide is substantially equivalent to other legally marketed class II medical devices under Product Codes KNT. Specifically, the subject device is substantially equivalent to the ViSiGi 3D (K130483).

The GLG has the identical indications for use as the ViSiGi 3D exception for “serve as a sizing guide”. The GLG is not used as a sizing guide.

Both the GLG and ViSiGi 3D are available in size 36 Fr and are of similar lengths (100cm compared to 107cm).

The main differences between the GLG and ViSiGi 3D are:

- The subject device has a second lumen with a lightwire for illumination.
- The subject device is provided sterile whereas the ViSiGi 3D is provided non-sterile. Both devices are for single patient usage.
- The subject device is composed of PVC as opposed to predicate is composed of thermoplastic Elastomer (Styrene-Ethylene – Butylene – Styrene) tube with LDPE valve connector.

The Innervision transillumination light bougie system (K964561) is also being included as a reference device for the illumination function. The transillumination system is available in 40 Fr, 50 Fr, and 56 Fr and can be connected to a commercially available light source. The GLG can also be connected to a commercially available light source.

This difference does not raise different questions of safety or efficacy. The GLG is as safe and effective as its predicate device.

Performance Data

The subject device has been subjected to and passed the testing outlined in the non-clinical performance testing table.

Non-Clinical Performance Testing Table

Test	Standard	Comments
Blood Interactions	ISO 10993-4	The testing concluded that the device does not exhibit hemolytic activity.
Cytotoxicity	ISO 10993-5	The testing concluded that the device has a rating of "1", which is slight reactivity.
Intradermal Reactivity	ISO 10993-10	The testing concluded that the device does not show any intradermal reactivity.
Irritation and Sensitizing Effect	ISO 10993-10	The testing concluded that the device does not show any skin sensitization.
Acute Systemic Toxicity	ISO 10993-11	The testing concluded that the device does not show increased toxic effects.
Ethylene Oxide Residuals	ISO 10993-7	The testing concluded that the EO residuals met requirements in ISO 10993-7. (less than 0.05 mg/instrument in one study and less than 0.9888 mg/instrument in another study).
Sterilization Validation	ISO 11135-1:2014	The validation confirmed that the EO cycles utilized for sterilization produce medical devices with a Sterility Assurance Level of 10^{-6}.
Tightness and Strength of Connector and Drain Connection	EN 1618:1997	The testing confirmed that catheter can within 60 seconds with weights attached to it and that there were no air bubbles visible during testing.
Heat Emission Testing	N/A	Study #1 The testing confirmed that the proximal end and distal tip temperature of the lightwire does not get hot or produce a temperature that would cause burn injuries. The testing was performed using a standard xenon light source at maximum setting. The maximum temperature was 24.5C at distal tip and 29.5C at proximal tip. Study# 2 The testing was conducted using the external device temperature. The testing was extended to 5 hours to well exceed any usage of the device. The

		testing used both a portable battery powered light source and a stationary light source. The maximum temperature was 22.0C at 4 hours for portable light source and 21.5C at 5 hours for stationary light source.
Aging Study	ISO 11607-1 ISO 11607-2 ASTM F88	An aging study was conducted real time to support 5 year shelf life. The testing included chemical stability (alkalinity, acidity, and reductive compounds). Packaging integrity testing include verification of intact seals, water permeability, seal strength, visual and dimensional. Additionally sterility testing was performed. Additional accelerated aging study performed to verify light wire stability that that no change to structure, flexibility, light intensity or color.
Design Verification including dimensional, strength and tightness of joints, gravitational flow	N/A	Dimensions, strength and tightness of joints and gravitational flow were verified during design verification.
Catheter – Test Methods for Kinking of Single Lumen Catheters and Medical Tubing	EN 13868	Used as a reference to test methodology
Test methods for common properties for catheters other than intravascular catheters	EN 1618	Used as a reference to method methodology.

Clinical Testing

The device was used in 112 surgeries of sleeve gastrectomy. All patients met the category of morbid obesity and ages 19 – 62 years. The study was conducted by Dr. Naser in Poland. There were no safety issues or complications.

Conclusions

The Nasmed GLG is as safe and effective as the predicate and reference devices. The Nasmed GLG has similar indications for use (except not used for sizing). The device has the same principles of operation and technological characteristics, as the predicate devices. There are only minor differences that do not alter its therapeutic purpose or raise new issues of safety or effectiveness, and performance data demonstrate that the GLG is as safe and effective as the predicate device. The non-clinical testing performed demonstrate that the subject device is as safe and effective and performs at as safely and effectively as the predicate device. Furthermore the usability study demonstrates successful usage in 112 surgeries. Thus, the GLG is substantially equivalent to the predicate devices.