October 30, 2024

Lagis Enterprise Co., Ltd.
Lynn Chen
Regulation Affairs
No. 29, Gong 1st Rd., Dajia Dist.
Taichung City, 43762
Taiwan

Re: K240334
Trade/Device Name: LAGIS Endoscopic Instruments - Grasper (DI-5670-33D, DI-5670-45D, DI-5716-33D, DI-5716-45D, DI-5719-33D, DI-5731-33D, DI-5731-45D, DI-5901-33D, DI-5901-45D)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 4, 2024
Received: October 4, 2024

Dear Lynn Chen:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.10.30 14:35:14 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control 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)*

K240334

Device Name

LAGIS Endoscopic Instruments - Grasper (DI-5670-33D, DI-5670-45D,
DI-5716-33D, DI-5716-45D,
DI-5719-33D,
DI-5731-33D, DI-5731-45D,
DI-5901-33D, DI-5901-45D)

Indications for Use *(Describe)*

The LAGIS Endoscopic Instruments-Grasper has applications in a variety of minimally invasive procedures to facilitate grasping and mobilization of tissue.

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

Submitted By:	Lagis Enterprise Co., Ltd. No. 29, Gong 1st Rd., Dajia, Taichung 437, Taiwan
Contact Person:	Lynn Chen TEL: +886-4-26820767 #4191 FAX: +886-4-26820766
Date Prepared:	February 1st, 2024
Device Name:	Endoscopic Instruments - Grasper
Trade Name: (Proprietary Name)	LAGIS Endoscopic Instruments - Grasper
Common Name of the Device:	Endoscopic Instrument
Classification Name:	Laparoscope, General & Plastic Surgery (21 CFR 876.1500, Product Code GCJ)
Predicate Device:	510(k) Number - K012625 Product Code –GEI Submitter - ALLIANCE MEDICAL CORP. Trade Name - Reprocessed Unipolar Laparoscopic/Endoscopic Instruments
Description:	The **LAGIS Endoscopic Instruments - Grasper** is a single use device sterilized by ethylene oxide. It is composed of an insulating shaft, a rotation knob, grasping forceps, and a ratchet handle. The 5 mm diameter insulating shaft is designed for use through appropriate size trocars. The rotation knob located on the handle rotates the insulating shaft 360 degrees in either direction for better maneuverability. With the ratchet handle, the grasping forceps are allowed to be locked in place. The grasping forceps are activated by compression and release of the ring of the handle.
Indications For Use:	The **LAGIS Endoscopic Instruments - Grasper** has applications in a variety of minimally invasive procedures to facilitate grasping and mobilization of tissue.

Technological Characteristics	The subject device, **LAGIS Endoscopic Instruments - Grasper**, is substantially equivalent to the predicate device. Both devices have the same intended use, which is to facilitate tissue grasping and mobilization during minimally invasive surgical procedures. The subject device includes additional grasping forceps tip types and a wider tip opening distance. However, these differences do not raise any safety or performance issues, as the device maintains the same functionality. The subject device also has a longer shaft length and generates greater grip force. These differences are minor and do not introduce new questions regarding safety or effectiveness, as confirmed by performance testing, including bending and ex vivo tissue testing. The materials used in the subject device are similar to those in the predicate device and have been tested for cytotoxicity, sensitization, irritation, and systemic toxicity per ISO 10993 and 21 CFR Part 58 requirements.
Performance Summary:	Performance bench tests were conducted to verify the design characteristics and confirm that the device functions as intended. These studies included assessments of biocompatibility, sterilization validation, material characteristics, and functional performance, along with bending and ex vivo tissue testing. The test results showed that the device performed acceptably compared to the predicate device in terms of grasping force, tip hardness, corrosion resistance, mobilization, and bending performance, among other parameters.
Conclusions:	The **LAGIS Endoscopic Instruments - Grasper** has the same intended use and design, specifications and properties, principles of operations, and similar range of sizes as the predicate devices, the Reprocessed Unipolar Laparoscopic/Endoscopic Instruments. The **LAGIS Endoscopic Instruments - Grasper** has similarities in technological characteristics to its predicate device. The technological similarities are all supported by performance activities and demonstrate that the device functions as intended. These differences in technological characteristics do not raise different questions of safety and effectiveness. After analyzing all testing data and comparing it with the predicated device, it can be concluded that the **LAGIS Endoscopic Instruments - Grasper** is substantially equivalent to the predicate device.