May 20, 2026

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

Re: K253134
Trade/Device Name: LAGIS Endoscopic Instruments- Scissors (EI-330S EI-330S-T EI-330MS EI-330MS-T)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 16, 2026
Received: April 17, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.20 14:36:54 -04'00'

Colin Kejing Chen, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253134

Please provide the device trade name(s).

LAGIS Endoscopic Instruments- Scissors

Please provide your Indications for Use below.

The LAGIS Endoscopic Instruments- Scissors have applications in minimally invasive procedures for cutting and cauterization of tissue.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

510(k) Summary_K253134

510(k) Summary

Submitted By:	Lagis Enterprise Co., Ltd. No. 29, Gong 1st Rd., Dajia, Taichung 437, Taiwan
Contact Person:	Lynn Chen TEL: +886-4-26820790 #2078 FAX: +886-4-26820737
Date Prepared:	May 15th, 2026
Device Name:	Endoscopic Instruments- Scissors
Trade Name: (Proprietary Name)	LAGIS Endoscopic Instruments- Scissors
Common Name of the Device:	Endoscopic Instruments- Scissors
Classification Name:	Electrosurgical, cutting & coagulation & accessories (21 CFR 878.4400, Product Code GEI)
Regulatory Class:	Class II
Panel:	General & Plastic Surgery
Predicate Device:	Trade Name - ENDOPATH™ Endoscopic Instruments 510(k) Number - K984240 Product Code - GEI Class - II Submitter - ETHICON ENDO-SURGERY, INC
Description:	The **LAGIS Endoscopic Instruments- Scissors** are comprised of a handle, a rotation knob, an insulated shaft, a pair of tips, and a cautery connector. The rotation knob located on the handle rotates the shaft 360°. To reposition the tips, turn the rotation knob. The tips are closed and opened by squeezing and releasing the handles. The cautery connection located on the top of the handle may be used for unipolar cautery when attached to standard cautery cables and their generators.
Indications For Use:	The **LAGIS Endoscopic Instruments- Scissors** have applications in minimally invasive procedures for cutting and cauterization of tissue.

Technological Characteristics:

Same as predicate devices, when the handles of the **LAGIS Endoscopic Instruments- Scissors** are compressed or released, the instrument tip close or open accordingly. The rotating knob located on the handle can be turned for rotating the shaft 360 degrees in either direction. A monopolar electrical connector extending from the handle allows for connection with a standard cable to a proper generator. Both devices have almost the same intended use, which is to facilitate cutting or transection of tissue during minimally invasive surgical procedures. Minor differences in length of tip, working length, voltage and electric safety standard do not affect substantial equivalence to the predicate device. The materials are comparable to the predicate device and meet the requirements of ISO 10993 and 21 CFR Part 58.

Device	**LAGIS Endoscopic Instruments- Scissors**	**Predicate Device (K984240)**
Product Code	GEI	GEI
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Device Classification	II	II
Intended Use	The LAGIS Endoscopic Instruments- Scissors have applications in minimally invasive procedures for cutting and cauterization of tissue.	The ENDOPATH™ Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.
Single Use Only	Yes	Yes
Length of tip	10/17mm	17mm
Working length	320/330 mm	330 mm
Voltage	2600V	3000V
Max Power Output	50W (cutting and coagulation)	Unknown
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993
Electric Safety	IEC60601-1-2 IEC TS 60601-4-2 IEC 60601-1 IEC 60601-2-2	IEC60601-1-2 IEC 60601-1 IEC 60601-2-2
Sterilization	Ethylene Oxide (ISO 11135)	Gamma (ISO 11137)

Performance Test Summary:

Performance bench tests were carried out to verify design characteristics and to ensure that the device can be used as intended. The studies included biocompatibility, electrical safety sterilization validation, material characteristics, functional performance characteristics and Thermal effect study of the devices.

- **Biocompatibility testing** was conducted following ISO 10993-1 and FDA's guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

- **Electric Safety testing** was conducted following IEC60601-1-2, IEC TS 60601-4-2, IEC 60601-1, IEC 60601-2-2 and FDA's guidance document, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery".
- **Sterilization validation** was performed according to ISO 11135.
- **Functional performance characteristics** were assessed through testing, including transecting the membrane, bending, dielectric withstand voltage and electrical continuity performances.
- **Thermal effect study** was conducted to evaluate thermal spread and tissue effects in accordance with FDA's guidance document, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery".

All tests met the predefined acceptance criteria. The testing identified no new questions of safety and effectiveness.

Conclusions: The **LAGIS Endoscopic Instruments- Scissors** has the same intended use and design, specifications and properties, principles of operations, and similar range of sizes as the predicate devices, the ENDOPATH™ Endoscopic Instruments (Scissors 5DCS). The **LAGIS Endoscopic Instruments- Scissors** has similarities in technological characteristics to its predicate device. The technological similarities are all supported by performance activities, which 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- Scissors** is substantially equivalent to the predicate device.