DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2015

Lagis Enterprise Company, Ltd
Ms. Cora Chen
RD Staff
No. 29, Gong 1st Road,
Dajia, Taichung 437
Taiwan

Re: K141902
Trade/Device Name: Lagis Endoscopic Instruments Disposable Grasper
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 20, 2015
Received: April 23, 2015

Dear Ms. 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 (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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141902

Device Name
Lagis Endoscopic Instruments Disposable Grasper

Indications for Use *(Describe)*
The Lagis Endoscopic Instruments Disposable Grasper has application in a variety of general, urologic, gynecologic and endoscopic procedure for grasping and clamping of tissue and small tubular structures.

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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Section 5: 510(k) Summary

SUBMITTED BY:	Lagis Enterprise Co., Ltd. No. 29, Gong 1st Rd., Dajia, Taichung 437, Taiwan
CONTACT PERSON:	Cora Chen 886-4-26820767 #3111 886-4-26820756
DATE PREPARED:	April 20, 2015
SUBJECT DEVICE:	Lagis Endoscopic Instruments Disposable Grasper
TRADE NAME:	Lagis Endoscopic Instruments
COMMON NAME:	Endoscopic Instruments
CLASSIFICATION NAME:	General & Plastic Surgery (21 CFR 876.1500, Product Code: GCJ)
PREDICATE DEVICE:	K930933: ENDOPATH® Endoscopic Surgical Instruments
DEVICE DESCRIPTION:	The **Lagis Endoscopic Instruments Disposable Grasper** with 5mm diameter insulated shaft, 33cm in length, is designed for introduction and use through all appropriately sized trocar sleeves or larger sized trocar sleeves with the use of a converter.
INDICATION FOR USE:	The **Lagis Endoscopic Instruments**

Disposable Grasper has applications in a variety of general, urologic, gynecologic, and endoscopic procedures for grasping and clamping of tissue and small tubular structures.

TECHNOLOGICAL CHARACTERISTICS:

Same as predicate devices, the **Lagis Endoscopic Instruments Disposable Grasper** has a pair of plastic handles, which are compressed and released to close or open the instrument forceps. The rotation knob located on the handle rotates the shaft 360 degrees in either direction. Due to different functional requirements, the instrument forceps can be of various designs such as fenestrated/atraumatic/flat/ Endo-Clinch/Babcock/CROCE-OLMI grasping forceps. The materials of construction are similar to the predicate devices and are satisfactorily tested for cytotoxicity, sensitization, intracutaneous reactivity and systematic toxicity per ISO 10993 and 21 CFR, Part 58 requirements.

PERFORMANCE 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, sterilization, validation, material characteristics, functional and performance characteristics of the devices. Test results demonstrated acceptable results with respect to predicate devices in corrosion and bending performances, etc.

CONCLUSIONS:

Based on the information provided herein and the Decision-Making Process Chart (Section 12.2), we conclude that the **Lagis Endoscopic Instruments Disposable Grasper** is safe, effective and performs well as intended, and also substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.