October 16, 2023

Hunan Life Technology Co., Ltd.
Fu Wang
Official Correspondent
4th floor, Building 10, Innovation and Entrepreneurship
Center, 31 Dongfeng Road, Heping Street, Xiangtan Economic D
HuNan, 411199
China

Re: K231725
Trade/Device Name: Laparoscope (4KA0, 4KA0R, 4KA30, 4KA30R, 4KA45, 4KA45R)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 11, 2023
Received: September 11, 2023

Dear Fu Wang:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.10.16 08:26:23 -04'00'

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231725

Device Name
Laparoscope (4KA04KA0R4KA304KA30R4KA454KA45R)

Indications for Use *(Describe)*
It is used in medical institutions for observation and imaging in abdominal surgery by entering the human body through the wound.

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

Date Prepared: April. 11st, 2023
Manufacturer: Hunan Endoso Life Technology Co., Ltd.
4th floor, Building 10, Innovation and Entrepreneurship Center, 31 Dongfeng Road, Heping Street, Xiangtan Economic Development District, HuNan, China 411199
Contact person：Wang Fu
Title: Director
Tel: （86）0731-52331999
Email: services@endoso.com.cn
Or wangfu@endoso.com.cn

Identification of the Device:

Proprietary/Trade Name:	Laparoscope
Model：	4KA0、4KA0R、4KA30、4KA30R、4KA45、4KA45R
Common name:	Laparoscope
Classification Name:	Laparoscope, General & Plastic Surgery
Regulatory Number:	21 CFR Part 876.1500
Product Code:	GCJ
Device Class:	Class II
Review Panel:	General & Plastic Surgery

Identification of the Legally Marketed Predicate Device:

Trade Name:	O-Mec Laparoscopes 690 Series
Classification Name:	Laparoscope, General & Plastic Surgery
Regulatory Number:	21 CFR Part 876.1500
Product Code:	GCJ
Device Class:	Class II
Review Panel:	General & Plastic Surgery
Submitter/510(k) Holder:	Qingdao O-Mec Medical Technology Co., Ltd.
Clearance:	K201151

This predicate has not been subject to a design-related recall.

Device Description:

The Laparoscope (Model: 4KA0、4KA0R、4KA30、4KA30R、4KA45、4KA45R) is used in medical institutions. Laparoscopes are tubular optical instruments used to visualize or image a patient's anatomy during minimally invasive, endoscopic procedures for examination, diagnosis or therapy. The Laparoscope transmits light in both the visible and near infrared spectrum to illuminate and image the anatomy, then

forms and relays the image of the surgical site to a camera system for processing and display.

Indications for Use:
It is used in medical institutions for observation and imaging in abdominal surgery by entering the human body through the wound.

Substantial Equivalence:
The Laparoscope employs the same fundamental scientific technology as its predicate device, as below table:

	Subject Device	**Predicate Device**	**Comparison**
K Number	**--**	**K201151**	
Name	Laparoscope	O-Mec 690 Series Laparoscopes	/
Model	4KA0、4KA0R、4KA30、4KA30R、4KA45、4KA45R	690-331000H, 690-331030H, 690-300500H, 690-300530H	/
Manufacturer	Hunan Endoso Life Technology Co., Ltd.	QINGDAO O-MEC MEDICAL TECHNOLOGY CO., LTD.	/
Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery	Same
Product Code	GCJ	GCJ	Same
Indications For Use			
Intended Use	It is used in medical institutions for observation and imaging in abdominal surgery by entering the human body through the wound.	The O-Mec Laparoscopes 690 Series (Models, 90-331000H, 690-331030H, 690-300500H, 690-300530H) are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments.	Similar
Working place/User	Use in a hospital environment by trained surgical physicians	Use in a hospital environment by trained	Same

	Subject Device	Predicate Device	Comparison
K Number	**--**	**K201151**	
	who are familiar with endoscopic procedures.	surgical physicians who are familiar with endoscopic procedures.	
Population	Adult	Adult	Same
Physical Characteristics			
Maximum width of insertion section	Φ10mm	Φ10.1mm	Similar
Working length	345mm±3%.	334mm	Similar
Optical Characteristics			
Field of view	80°±15%	75°	Similar
Direction of view	30	30°	Same
Clear Observation Range	3mm～200mm	25-150mm	Similar
Resolution power	7lp/mm	7lp/mm	Same
Lighting Edge Uniformity	Inspection within the effective depth of field, the illumination spot should be filled with all direction of view, and the illuminance at 90% of the maximum direction of view should be uniform. Select four orthogonal azimuth in this direction of view for testing. Uniformity should be ≤25%.	Inspection within the effective depth of field, the illumination spot should be filled with all direction of view, and the illuminance at 90% of the maximum direction of view should be uniform. Select four orthogonal azimuth in this direction of view for testing. Uniformity should be ≤25%.	Same
Patient Contacting Materials			
General material type of main patient-contact part	Compliance with ISO10993-1	Compliance with ISO10993-1	Same
Duration and type of contact	"Surface –Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	"Surface –Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	Same
Patient-Contacti	Stainless Steel 304	Stainless Steel 304	Similar

	Subject Device	Predicate Device	Comparison
K Number	**--**	**K201151**	
ng Materials	Optical Glass Sapphire Epoxy Glue	Stainless Steel 316L Optical Glass Sapphire Epoxy Glue	
Sterilization Methods			
Number of Users	Reusable	Reusable	Same
Cleaning	Manual and Automated	Manual and Automated	Same
Disinfection	Manual and Automated	Manual and Automated	Same
Sterilization	Autoclave, STERRAD® 100NX	Autoclave, STERRAD® 100NX	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same
Biocompatibility	No Cytotoxicity	No Cytotoxicity	Same
	No Irritation to Skin	No Irritation to Skin	Same
	No significant evidence of sensitization	No significant evidence of sensitization	Same
	No pyrogen	No pyrogen	Same
	No acute Systemic Toxicity	No acute Systemic Toxicity	Same

Summary of Testing:

Test	Method	Result
Electrical Safety and EMC	• ANSI/AAMI ES:60601-1:2005/A2:2010 • IEC 60601-2-18:2009	PASS
Packaging	• ASTM D4169:2016	PASS
Biocompatibility	• ISO 10993- 1:2018 • ISO 10993-5:2009 • ISO 10993- 10:2010 • ISO 10993- 11:2017 • FDA Guidance: Use of International Standard ISO10993-1	PASS

Cleaning, Disinfection and Sterilization	• AAMI TIR 12:2020 • AAMI TIR 30: 2011/(R)2016 • ISO 17664- 1:2021 • ISO 17665-1: 2006 FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling	PASS
Performance - Bench	• Optical and mechanical verification in accordance with device input specifications and comparison to predicate device • ISO 8600- 1:2015 • ISO 8600-3：2019 • ISO 8600-4：2014 • ISO 8600-7：2012	PASS
Design Validation	• IEC 62366-1:2020 • In accordance with device user needs	PASS

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Laparoscope is substantially equivalent to the predicate device.