September 24, 2025

EndoRobotics Co., Ltd.
℅ Jonghyun Kim
Official Correspondent
Global Medical Standard Consulting Co., Ltd.
66, Cheongcho-ro,
Deogyang-gu, Goyang-si
Gyeonggi-do, 10543
Korea, South

Re: K244029
Trade/Device Name: ROBOPERA (ER-R-002); ROBOPERA (ER-R-003)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF, FDS, NAY
Dated: December 30, 2024
Received: August 25, 2025

Dear Jonghyun Kim:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K244029

Device Name
ROBOPERA (ER-R-002);
ROBOPERA (ER-R-003)

Indications for Use *(Describe)*
The ROBOPERA is intended to hold and lift the tissue and mucosal membrane within the esophagus, stomach, colon, and rectum of the gastrointestinal tract, excluding the small intestine, during endoscopic surgical procedures. It is intended to be used by trained physicians in a hospital.

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
K244029

ENDOROBOTICS

510(k) Summary - K244029

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

December 30, 2024

2. Submitter's Information [21 CFR 807.92(a)(1)]

- **Name of Manufacturer:** EndoRobotics Co., Ltd.
- **Address:** 14-15 floor, 57, Deahk-ro, Jongno-gu
  Seoul Korea, South (Zip: 03082)
- **Contact Name:** Jihwan Kim / Regulatory Affairs Manager
- **Telephone No.:** +82-70-4129-9634
- **Email Address:** jihwankim@endorobo.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- **Trade Name:** ROBOPERA (ER-R-002); ROBOPERA (ER-R-003)

Common Name	Colonoscope and Accessories
Regulation Name	Endoscope and accessories
Regulation Number	21 CFR 876.1500
Product Code	FDF, FDS, NAY
Device Class	II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

Predicate Device

- **510(k) Number:** K173919
- **Applicant:** Human Extension Ltd.
- **Classification Name:** Endoscope and accessories
- **Trade Name:** HX Device
- **Product Code:** GCJ, NAY

Reference Device

- **510(k) Number:** K152802
- **Applicant:** Micro-Tech (Nanjing) Co., Ltd.
- **Classification Name:** Endoscope and accessories
- **Trade Name:** Grasping Forceps
- **Product Code:** OCZ

5. Description of the Device [21 CFR 807.92(a)(4)]

This product consists of a driving unit, an instrument, and a controller. The forceps of the instrument are mounted on the outer tip of the endoscope, the cartridge is inserted into the driving unit, and the controller is mounted on the endoscope boot.

The user can perform four operations (Grip, Wrist, Arm, Roll) of the instrument (Articulated Basic Gripper G), and three operations (Grip A, B, Arm, Roll) of the instrument (Articulated Dual Gripper G) through the controller.

In this product, the power generated through the motor in the driving unit is transmitted to the forceps in a physical way through the instrument cartridge and cable, and the forceps can perform four movements: grip, wrist, arm, and roll using the transmitted force to catch and lift and fix the mucous membrane of the lesion during mucosal incision or resection using an endoscope. In addition, after mucosal incision and resection, it can play a role of assisting in clipping by catching and collecting a part of the mucous membrane.

- **ROBOPERA Configurations:**

Model Name	Description
ER-R-002	Driver Unit + Instrument (Articulated Basic Gripper G)
ER-R-003	Driver Unit + Instrument (Articulated Dual Gripper G)

6. Indications for use [21 CFR 807.92(a)(5)]

The ROBOPERA is intended to hold and lift the tissue and mucosal membrane within the esophagus, stomach, colon, and rectum of the gastrointestinal tract, excluding the small intestine, during endoscopic surgical procedures. It is intended to be used by trained physicians in a hospital.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(4)]

The table below presents comparisons between the subject device (ROBOPERA) and the legally marketed predicate devices (K173919):

[Table 1. Comparison of Subject Device to Predicate Device]

	Subject Device	Predicate Device	Reference Device	Remark
Product Name	ROBOPERA	HX Device	Grasping Forceps	-
Product Code	FDF, FDS, NAY	GCJ, NAY	OCZ	-
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Same
Regulatory Class	Class II	Class II	Class II	Same
Indications for Use	The ROBOPERA is intended to hold and lift the tissue and mucosal membrane within the esophagus, stomach, colon, and rectum of the gastrointestinal tract, excluding the small intestine, during endoscopic surgical procedures. It is intended to be used by trained physicians in a hospital.	The HX Device is intended to assist in the accurate control of HX laparoscopic Instruments including needle holder and grasper, for endoscopic manipulation of tissue, including grasping, approximation, ligation, suturing, during laparoscopic surgical procedures. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions For Use.	Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal tract.	Same
Prescription Use	Prescription Use only	Prescription Use only	Prescription Use only	Same
Operational Environments	Hospital	Hospital	Hospital	Same
Mode of Operation	Electromechanically operated, software controlled	Electromechanically operated, software controlled	Manually operated	Same

Component	Driver unit, Controller (A, B), Instrument (A, B), Power cable, Controller Holder. ENJECT Tool, Sleeve Tube	Handpiece and compatible instruments (Grasper, Needle Holder); Arc, Pads, Spacer, Power Cable	Jaws, spring sheath, finger ring	Similar
Articulation range	Variable	Variable	None	Similar
Material	Stainless steel	Stainless steel	Stainless steel	Same
Single Use/Reusable	Single Use	Single Use for Instrument	Single Use	Same
Sterilization method	Ethylene Oxide Gas Sterilization	Ethylene Oxide Gas Sterilization	Ethylene Oxide Gas Sterilization	Same
Safety	IEC 60601-1:2005+A1:2012	IEC 60601-1:2005+A1:2012	None	Same
EMC	IEC 60601-1-2:2014 4th E	IEC 60601-1-2:2014 4th E	None	Same
Biocompatibility	ISO 10993-1	ISO 10993-1	ISO 10993-1	Same

The indications for use of the subject, predicate and reference device are similar, and they have the same intended use.

The subject, predicate and reference devices have similar technological features. However, as shown in the table above, there are technological differences between the subject, predicate and reference devices. The different technological characteristics of the subject device, as compared to the predicate and reference devices, do not raise different questions of safety and effectiveness.

8. PERFORMANCE DATA [21 CFR 807.92(b)(1)]

1) EMC, Wireless, and Electrical, Mechanical and Thermal Safety

The test results demonstrated that the proposed device complies with the following standards:

- Electrical Basic Safety and Essential Performance requirements in accordance with IEC 60601-1:2005/AMD2:2020
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014+A1:2020
- Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability in accordance with IEC 60601-1- 6:2010/AMD2:2020

2) Reprocessing, Sterility and Shelf-Life

- **Sterilization and shelf life testing**

The sterilization method has been validated to ISO 11135:2014, which has thereby determined the routine control and monitoring parameters.

EO/ECH residual test was performed according to ISO 10993-7:2008.

The shelf life (2 years) of the Single-Use Digital Flexible Ureteroscope is determined based on stability study which includes ageing test according to ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier.

3) Software

The software was designed and developed according to IEC 62304 software development process and was verified and validated. According to the guidance, we evaluated the level of Basic level documentation by identifying safety-related characteristics for device documentation level.

- The software information is provided in accordance with FDA guidance: Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff', issued on JUNE 2023.

4) Performance Testing

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Dimensional Attributes Verification	- Forceps Instrument Reliability Evaluation
- Device Motion Performance	- Instrument Corrosion
- Emergency Stop button	- Endoscope compatibility
- Forceps instrument articulation control test	- Forceps instrument motion performance test
- Controller performance test	- Eject tool performance test
- Tensile strength of connection between device components	

5) Human factor

Usability testing was conducted. Formative Test and Summative Test were conducted in accordance with IEC 62366-1:2015+AMD1:2020 CSV
(Medical devices – Part 1: Application of usability engineering to medical devices)

6) Animal Testing

This study was conducted in accordance with a study protocol written following FDA Guidelines. It aimed to evaluate the ability of the forceps to precisely and controllably dissect the submucosal layer during ESD based on real clinical scenarios.

The results of the animal validation tests showed that the preclinical animal study of the electrically powered endoscopic therapeutic forceps (ROBOPERA) was designed to assess the safety and efficacy of the device in the specific context of ESD. The study protocol focused on simulating real clinical scenarios to evaluate the forceps' ability to precisely and controllably dissect the submucosal layer and demonstrated substantially equivalent accuracy to the predicate device.

- The animal study information is provided in accordance with FDA guidance: General Considerations for Animal Studies Intended to Evaluate Medical Devices: Guidance for Industry and Food and Drug Administration Staff, issued on March 28, 2023

7) Biocompatibility

Biocompatibility studies, including irritation, cytotoxicity, and sensitization testing were performed in accordance with the 2020 FDA guidance document Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process", as follows:

- Cytotoxicity	ISO 10993-5:2009
- Sensitization	ISO 10993-10:2021
- irritation:	ISO 10993-23:2021
- Acute systemic toxicity	ISO 10993-11:2017
- material mediated pyrogenicity	ISO 10993-11:2017

The user-contacting materials were shown to be non-cytotoxic, non-irritating, non-sensitizing and non-acute.

8) Clinical Test Summary:

The subject of this premarket submission did not require clinical studies were considered necessary and performed.

9. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification EndoRobotics Co., Ltd. concludes that the ROBOPERA is substantially equivalent in safety and effectiveness to the predicate devices as described herein.