August 20, 2024

FINEMEDIX Co., Ltd.
Seok-Jun Ma
Official Correspondent
140-9, Yuram-Ro, Dong-Gu
Daegu, 41059
South Korea

Re: K242134
Trade/Device Name: ClearCap Distal Attachment
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: July 18, 2024
Received: July 22, 2024

Dear Seok-Jun Ma:

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,

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.

Submission Number *(if known)*

K242134

Device Name

ClearCap Distal Attachment

Indications for Use *(Describe)*

The ClearCap Distal Attachment has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy.

The ClearCap Distal Attachment is intended for the following:
• Gastrointestinal mucosal resection (endoscopic mucosal resection)
• Keeping the suitable depth of the endoscope's view field

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

July 18, 2024

1. Submitted by:

FINEMEDIX Co., Ltd.
140-9, Yuram-ro, Dong-gu, Daegu, 41059
Republic of Korea
Tel : 82-53-741-8388, Fax : 82-53-741-8168

2. US Agent/ Official Correspondent:

Priscilla Chung

LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, CA 92612
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

3. Device Name:

- Trade Name : ClearCap Distal Attachment
- Classification : Class II
- Classification Name : Endoscopy Distal Attachment Cap
- Product Code : OCX
- Regulation Number : 21 CFR 876.1500
- Review Panel : Gastroenterology/Urology

4. Predicate Device:

ClearCap Distal Attachment (K202616) by FINEMEDIX Co., Ltd.

5 Device Description:

The ClearCap Distal Attachment is a sterile distal attachment intended to improve endoscopic control and to help maintain the clear view by keeping a moderate distance from the tissues during endoscopic surgical procedures.
The ClearCap Distal Attachment is comprised of three main sections: an attaching portion, a distal portion and draining holes. The attaching portion is connecting portion of the attachment to an applicable endoscope; a distal portion is the ending portion of the attachment and the 2 draining holes on the sidewall are to discharge bleeding and some foreign matter.
Applicable lesions are both lower digestive tract (=gastrointestinal (GI) tract) and upper GI tract.
The model name FM-CC01, FM-CC05, FM-CC06 and FM-CC07 are for lower GI Tract, and FM-CC02, FM-CC03 and FM-CC04 are for upper GI tract.
It is available in various sizes of diameter to assure the compatibility of various endoscope outer diameters. The average contact time of the product and the mucosa of the human digestive tract is less than 1 hour. This device is supplied sterile for single-patient use and shall be not reused or re-sterilized.

6 Indications for Use Statement

The ClearCap Distal Attachment has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy.
The ClearCap Distal Attachment is intended for the following:
• Gastrointestinal mucosal resection (endoscopic mucosal resection)
• Keeping the suitable depth of the endoscope's view field

7 Substantial Equivalence Discussion:

7.1. Comparison Chart

A comparison of the technological characteristics between the subject and predicate devices is provided in the table below:

	Subject Device	Predicate Device
Company	Finemedix Co., Ltd.	Finemedix Co., Ltd.
Device Name	ClearCap Distal Attachment	ClearCap Distal Attachment
510(k) Number	K242134	K202616
Device Classification Name	Endoscope and accessories.	Endoscope and accessories.
Product Code	OCX	OCX
Regulation Number	876.1500	876.1500

Indications for Use	The ClearCap Distal Attachment has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy. The ClearCap Distal Attachment is intended for the following: • Gastrointestinal mucosal resection (endoscopic mucosal resection) • Keeping the suitable depth of the endoscope's view field	The ClearCap Distal Attachment has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy. The ClearCap Distal Attachment is intended for the following: • Gastrointestinal mucosal resection (endoscopic mucosal resection) • Keeping the suitable depth of the endoscope's view field
Principle of Operation	It is attached to the end of the endoscope device to maintain proper distance from the tissue and to ensure visibility by discharging bleeding and some foreign substances through two holes on the side.	It is attached to the end of the endoscope device to maintain proper distance from the tissue and to ensure visibility by discharging bleeding and some foreign substances through two holes on the side.
Materials	Thermoplastic Polyurethane (TPU)	Thermoplastic Polyurethane (TPU)
Outer Diameter	11.35mm, 11.8mm, 12.4mm, 13.4mm, 14.0mm, 15.0mm, 15.7mm	11.35mm, 11.8mm, 12.4mm, 13.4mm, 14.0mm, 15.0mm, 15.7mm
Inner Diameter for Connection to Endoscopy	13.2mm, 10.0mm, 9.5mm, 10.6mm, 11.6mm, 12.2mm, 13.9mm	13.2mm, 10.0mm, 9.5mm, 10.6mm, 11.6mm, 12.2mm, 13.9mm
Total Length	14.0mm	11.0mm
Inner Diameter of distal end	8.0mm	8.9mm, 9.4mm,10mm, 11mm,11.6mm,12.6mm, 13.3mm
Shape, Size and number of the draining hole	Oval Hole Ø3.55x2mm, 2 pieces	Round Hole Ø3mm, 2 pieces
Sterility	Sterilized by Ethylene Oxide	Sterilized by Ethylene Oxide
Reuse or not re-use	Single Use	Single Use
Similarities	The subject device is substantially equivalent to the predicate devices in Indications for Use, materials, dimensions, sterilization methods and principle of operation.	
Substantial Equivalence Discussion	The differences between the subject and the predicate devices are below: - Overall Length: The overall length is 14.00mm, which is 3.0mm longer than the predicate device. This additional length allows for better maintenance of a consistent distance between the mucosal layers. - Inner Diameter of distal end: The smaller distal end in conical shape makes it easier to access the dissected submucosal layer. - Shape of the drain: The number of draining holes is the same, but the draining holes have been modified to oval shape to facilitate suction function. We have conducted risk analysis and the verification and validation activities for the modifications, and the test results support that the differences do not raise any questions of substantial equivalence to the declared predicates.	

8. Non-clinical Tests

The ClearCap Distal Attachment and the predicate devices in the market have the substantially equivalent technological characteristics. Risks associated with the changes were identified and appropriate design controls implemented to mitigate the risks.
To validate the control of the risks, direct comparison testing between the subject device models and predicate device models for gap, endoscope compatibility and viewing, and suction function were performed.

9. Conclusion:

Based on the information provided herein and the test results, we conclude that the subject device is substantially equivalent to its predicate device.The nonclincal tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.