February 19, 2021

Finemedix Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, CA 92620

Re: K202616
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: December 22, 2020
Received: January 8, 2021

Dear April Lee:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
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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)*
K202616

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.

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510(k) Summary

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Device Information

- Trade Name: ClearCap Distal Attachment
- Regulation Name: Endoscope and accessories
- Product Code: OCX
- Panel: Gastroenterology/Urology
- Regulation Number: 21 CFR 876.1500
- Device Class: Class II
- Date Prepared: 02/18/2020

Predicate Devices:

Primary Predicate
K140315, US ENDOSCOPY DISTAL ATTACHMENT CAP by UNITED STATES ENDOSCOPY GROUP, INC

Reference Device
K162749, FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR by FUJIFILM Medical System U.S.A., Inc.

Indication 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

Device Description:

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-EC0001, FM-EC0005, FM-EC0006 and FM-EC0007 are for lower GI Tract, and FM-EC0002, EC0003 and EC0004 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.

Summary of Technological Characteristics:

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

	Subject Device	**Primary Predicate**	**Reference Device**
Company	Finemedix Co., Ltd.	United States Endoscopy Group Inc.	FUJIFILM Medical Systems U.S.A., Inc.
Device Name	ClearCap Distal Attachment	US Endoscopy Distal Attachment Cap	FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR
510(k) Number	NA	K140315	K162749
Device Classification Name	Endoscope and accessories.	Endoscope and accessories.	Endoscope and accessories.
Product Code	OCX	OCX	FDS, FDF
Regulation Number	876.1500	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 US Endoscopy Distal Attachment Cap has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy. The US Endoscopy Distal Attachment Cap is intended for the following: • Gastrointestinal mucosal resection (endoscopic mucosal resection) • Keeping the suitable depth of the endoscope's view field	The FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

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 one hole 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.
Appearance			
Materials	Thermoplastic Polyurethane (TPU)	Unknown	Silicone
Outer Diameter	11.35mm, 11.8mm, 12.4mm, 13.4mm, 14.0mm, 15.0mm, 15.7mm	Unknown	11.8mm, 13.0mm, 14.8mm
Maximum Diameter of attaching endoscope	9.4mm, 9.8mm, 10.5mm, 11.7mm, 12.2mm, 13.7mm, 13.9mm	Unknown	15.5mm, 16.5mm, 18.4mm
Total Length	11mm	Unknown	17mm
Inner Diameter of distal end	8.9mm, 9.4mm,10mm, 11mm,11.6mm,12.6mm, 13.3mm	Unknown	8.0mm
Size and number of the drain	Round hole Ø3mm, 2 piece	Round hole Unknown, 1 piece	Square hole 5.0mm X 1.25mm, 2 piece
Sterility	Sterilized by Ethylene Oxide	Sterilized by Ethylene Oxide	Unknown
Reuse or not re-use	Single Use	Single Use	Single Use
Similarities	The subject device is substantially equivalent to the predicate devices in Indications for Use, materials, dimensions, hole shape, sterilization methods and principle of operation.		
Differences	The differences between the subject and primary predicate are below: - Materials: While the material of the subject device is TPU, the material of the primary predicate is unknown, and material of the reference device is silicone. The subject material, TPU is a thermoplastic Polyurethane and has gained wide acceptance as an alternative to silicone. By performing the biocompatibility testing on the subject device, it is demonstrated that the subject device is biocompatible and substantially equivalent. - Number of the drain hole: The number of the drain hole is different; subject device has two drain hole pieces and the primary predicate has one drain hole piece. The two drain holes have only improved the discharge of bleeding and some foreign matter, and there are not directly connected part to the endoscope, so no other effects will occur. These differences do not raise any questions of substantial equivalence to the declared predicates.		

Non-clinical testing data:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017.
- Performance testing such as appearance, dimension, extractable substance and Endoscope Compatibility and Suction testing
- EO Sterilization residuals testing according to ISO 10993-7:2008
- Shelf Life Testing according to ASTM F1980

Below tests were performed on our own device and they can be leveraged for the subject device:

- EO Sterilization Validation Testing according to ISO 11737-1:2006 and ISO 11737-2:2009 referenced in K180363

The biocompatibility evaluation for ClearCap Distal Attachment was conducted in accordance with *ISO 10993-1*: *2009 "Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing within a Risk Management Process"* and FDA's biocompatibility guidance, *G95-1 Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (May 1, 1995).* The following tests were completed: Cytotoxicity, Sensitization, Intracutaneous reactivity, Acute Systemic Toxicity and Pyrogen Test.
Performance testing such as appearance and dimensions were performed as per Finemedix's design control system.
The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion:
The ClearCap Distal Attachment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate device. Therefore, the ClearCap Distal Attachment and its predicates are substantially equivalent.