March 6, 2019

FINEMEDIX CO., LTD.
% April Lee
Consultant
Withus Group, Inc.
106 Superior
Irvine, CA 92620

Re: K183289
Trade/Device Name: ClearGrasp Snare
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: FDI
Dated: January 29, 2019
Received: February 5, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 J. Antonino -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K183289

Device Name
ClearGrasp Snare

Indications for Use *(Describe)*
The ClearGrasp Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

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

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Device Information

- Trade Name: ClearGrasp Snare
- Common Name: Snare, Flexible
- Classification Name: Endoscopic electrosurgical unit and accessories
- Product Code: FDI
- Panel: Gastroenterology/Urology
- Regulation Number: 21 CFR 876.4300
- Device Class: Class II
- Date Prepared: 11/23/2018

Predicate Devices:
The subject device is substantially equivalent to the following predicate devices:

- K172729, Polypectomy Snare manufactured by Hangzhou AGS MedTech Co., Ltd.
- K151197, Lariat Snare by United States Endoscopy Group, Inc.
- K172758, Rotatable Snares, Non-Rotatable Snares by Zhejiang Chuangxiang Medical Technology Co., LTD.

Indication for Use:
The ClearGrasp Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

Device Description:
ClearGrasp Snare is a monopolar electrosurgical instrument intended for EMR which is Endoscopic Mucosal Resection by applying high-frequency current during endoscopic electrosurgical procedures. It is used for grasping and resecting the targeted lesion within the digestive tract by opening and closing the loop. Users can choose an oval or a crescent type based on their preference and the characteristic of the lesion. The loop sizes can be chosen in accordance with the size of the lesion and the rotational type helps approaching and grasping the lesion. There is a stiff type and soft type distinguished by the strength of loop.

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The device consists of a flexible Rope Wire and various size of loop, which can be extended and rotated from the flexible Catheter Tube using two handle control knobs such as Handle and Slider. When connected to an electrosurgical generator and activated, the loop delivers a monopolar electrical current to the surgical site. This device passes through the working channel of endoscope, and 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:

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**
Company	Finemedix Co., Ltd.	Hangzhou AGS MedTech Co., Ltd.	United States Endoscopy Group, Inc.	Zhejiang Chuangxiang Medical Technology Co., LTD.
Device Name	ClearGrasp Snare	Polypectomy Snare	Lariat Snare	Rotatable Snares, Non-Rotatable Snares
510(k) Number	NA	K172729	K151197	K172758
Device Classification Name	Endoscopic electrosurgical unit and accessories	Endoscopic electrosurgical unit and accessories	Endoscopic electrosurgical unit and accessories	Endoscopic electrosurgical unit and accessories
Product Code	FDI	FDI	FDI	FDI
Regulation Number	876.4300	876.4300	876.4300	876.4300
Indications for Use	The ClearGrasp Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.	The Polypectomy Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.	The Lariat snare is an electrosurgical device designed to be used to endoscopically grasp, dissect and transect tissue during GI endoscopic procedures.	The Polypectomy Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polys and tissue from within the gastrointestinal tract.
Principle of Operation	Monopolar electrosurgical instrument intended for EMR	Monopolar electrosurgical instrument intended for EMR	Monopolar electrosurgical instrument intended for EMR	Monopolar electrosurgical instrument intended for EMR

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Material	Loop	SUS 304	SUS 304	Unknown	Unknown
	Catheter Tube	PTFE	PTFE		
	Handle	ABS	ABS		
Components		Loop, Catheter Tube, Handle, Slider, Plug	Loop, Catheter Tube, Handle, Slider, Plug	Loop, Catheter Tube, Handle, Slider, Plug	Loop, Catheter Tube, Handle, Slider, Plug
Shape of Loop		Oval and Crescent	Oval, Polygon, Duck Bill, Hexagonal and Round	Oval, Hexagonal and Diamond	Oval, Hexagonal, Crescent, Round
Working Length		1600,1800,2200, 2400 mm	1800, 2300 mm	2300mm	1600, 1800, 2400mm
Loop Size		6,10,13,15, 24,30 mm	10,15,25,32 mm	6,10,30mm	10,15,22,25,32mm
Rotational/Non-Rotational		Both	Both	Non-Rotational	Both
Sterile/Non-Sterile		Sterile	Sterile	Sterile	Sterile
Sterilization Method		Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Single Use		Yes	Yes	Yes	Yes
Used with Electrosurgical Unit		Yes	Yes	Yes	Yes
Similarities		The subject device is substantially equivalent to the predicate device in Indications for Use, materials, components, shape of loop, rotationality, sterilization methods and principle of operation.			
Differences		The difference between the subject and primary predicate are shape of loop, working length, and loop size. To support the difference of the shape of loop such as the crescent shape and working length such as 1600 and 2400mm, we added the K172758 as the reference device. To support the difference of the loop size such as 6mm, we added the K151197 as the reference device. These differences do not raise any questions of substantial equivalence to the declared predicates.			

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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 and ISO 10993-11:2006
- Performance testing such as appearance, dimension, continuity, tensile strength test of electrode cable, withstand voltage, high frequency leakage current test of electrode cable according to IEC 60601-2-2:2017 and ANSI/AAMI HF18:2001
- EO Sterilization residuals testing according to ISO 10993-7:2008

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
- Shelf Life Testing according to ASTM F1980

The biocompatibility evaluation for ClearGrasp Snare 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, dimension, and continuity 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:

ClearGrasp Snare 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, ClearGrasp Snare and its predicate are substantially equivalent.