November 1, 2018

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

Re: K180363
Trade/Device Name: Clear-Tip EUS-FNA
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: September 18, 2018
Received: September 20, 2018

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 R. Kreitz -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)*
K180363

Device Name
Clear-Tip EUS-FNA

Indications for Use *(Describe)*
The Clear-Tip EUS-FNA is used with an ultrasound endoscope for fine needle biopsy of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal 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.

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510(k) Summary

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Device Information

- Trade Name: Clear-Tip EUS-FNA
- Common Name: Biopsy needle
- Classification Name: Gastroenterology-urology biopsy instrument
- Product Code: FCG
- Panel: Gastroenterology/Urology
- Regulation Number: 21 CFR 876.1075
- Device Class: Class II
- Date Prepared: 02/05/2018

Predicate Devices:

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

- K142688, Cook Ireland EchoTip Procore® HD Ultrasound Biopsy Needle by Cook Ireland Ltd.

Indication for Use:

The Clear-Tip EUS-FNA is used with an ultrasound endoscope for fine needle biopsy of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.

Device Description:

Clear-Tip EUS-FNA is used in conjunction with an ultrasound endoscope.
It consists of a handle section and insertion section. The handle section is connected to the endoscope's instrument channel port. The insertion section is composed of the Catheter Tube, Needle, and Stylet. A Syringe is attached to the aspiration port on the handle section to aspirate the specimen that was punctured with the Needle. Syringe and Stopcock are accessories to provide and control the vacuum suction to aspirate the tissue specimen. They also can be used to expel the samples after the procedure.
Clear-Tip EUS-FNA is offered in various needle gauges for insertion and aspiration. The available needle gauge sizes of 19, 22 and 25 gauges. The Needle which is dimpled for ultrasonic visualization is advanced into the target site for aspiration. The device allows for adjustment of the length of the Catheter Tube and Needle to enable the user to adjust for the working length of the endoscope and to control

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needle insertion depth. It is preloaded with a Stylet to aid in inserting the Needle which is removed for injection and aspiration.
This device passes through the working channel of endoscope, and the average contact time with 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. This device is for Rx used only.

Summary of Technological Characteristics:

		Subject Device	**Primary Predicate**
Company		Finemedix Co., Ltd	Cook Ireland Ltd.
Device Name		Clear-Tip EUS-FNA	Cook Ireland EchoTip Procore® HD Ultrasound Biopsy Needle
510(k) Number		N/A	K142688
Device Classification Name		Gastroenterology-urology biopsy instrument	Gastroenterology-urology biopsy instrument
Product Code		FCG	FCG
Regulation Number		21 CFR 876.1075	21 CFR 876.1075
Intended Use		The Clear-Tip EUS-FNA is used with an ultrasound endoscope for fine needle biopsy of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.	The device is used with an ultrasound endoscope for fine needle biopsy of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.
Material	Needle	Stainless Steel Alloys	Stainless Steel Alloys
	Stylet	Nickel-Titanium Alloys (Nitinol)	Nickel-Titanium Alloys (Nitinol)
Components		Catheter Tube, Needle, Stylet, Syringe, Stopcock	Catheter Tube, Needle, Stylet, Syringe, Stopcock
Gauge size		19,22,25 ga	19,20,22,25 ga
Dimple pattern of Echo part		Spiral shape	High Definition dot shape

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Needle Design	Non-bevel type, Bevel type	Bevel type
Stylet tip options	Ball tip	Ball tip or Bevel tip
Compatibility with an ultrasound endoscope	Yes	Yes
Minimum accessory channel (Ultrasound endoscope)	2.0	2.0
Use with a syringe and stopcock	Yes	Yes
Principle of Operation	Manual, sampling using cutting and aspiration	Manual, sampling using cutting and aspiration
Method of needle and sheath adjustment	Handle part	Handle part
Needle length adjustment range	0 ~ 8cm	0 ~ 8cm
Sheath extension adjustment range	3 ~ 5cm	3 ~ 5cm
For single use	Yes	Yes
Sterility	EO Gas sterilization	EO Gas sterilization
Shelf Life	3 years	3 years
Similarities	Both subject and predicate devices are substantially equivalent in the intended use, Material, Components, Gauge size, Design, Stylet tip option, Compatibility with an ultrasound endoscope, Minimum accessory channel (Ultrasound endoscope), Use with a syringe and stopcock, Principle of Operation, Method of needle and sheath adjustment, Needle length adjustment range, Sheath extension adjustment range, for single use, Sterility, and Shelf Life as charted.	
Differences	The difference between the subject and predicate devices is “Dimple pattern of Echo part”. The pattern of the subject device is spiral shape, while the one of the predicate device is dot shape. The spiral shape is to allow visualization of the needle more clearly and easy positioning than dot shape under endoscopic ultrasound. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.	

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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, operation, elasticity, bending strength test, and Tensile strength test
- Physical and Chemical Safety Testing such as color and transparent, pH, KMnO4 Consumption, Non-Volatile residue, ultraviolet absorption, heavy metal as lead, EO Sterilization residuals test, and sterility test
- EO Sterilization Testing according to ISO 11737-1:2006 and ISO 11737-2:2009
- Shelf Life Testing according to ASTM F1980

The biocompatibility evaluation for Clear-Tip EUS-FNA 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 and Acute Systemic Toxicity.

The device specific guidance document was consulted in preparing this premarket submission, *Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology.* Performance testing such as appearance, dimension, operation, elasticity, bending strength test, and Tensile strength test 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:

Clear-Tip EUS-FNA 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, Clear-Tip EUS-FNA and its predicate are substantially equivalent.