June 30, 2023

Finemedix Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, CA 92612

Re: K231267
Trade/Device Name: ClearTip
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: FCG
Dated: April 28, 2023
Received: May 2, 2023

Dear Priscilla Chung:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231267

Device Name
ClearTip

Indications for Use *(Describe)*
The ClearTip is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree and Gastrointestinal Tract, (e.g., lymph nodes, abnormal tissue in the mediastinum).

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

(K231267)

June 8, 2023

1. Submitted by:

FINEMEDIX Co., Ltd.
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2. US Agent/ Official Correspondent:

Priscilla Chung

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3. Device Name:

- Trade Name : ClearTip
- Classification : Class II
- Classification Name : Biopsy Needle
- Product Code : FCG
- Regulation Number : 876.1075
- Review Panel : Gastroenterology/Urology

4. Predicate Device:

- Primary Predicate Device: SonoTip Pro and Pro Flex EBUS-TBNA Needle System (K133763) by Medi-Globe Corporation
- Reference Predicate Device: Clear-Tip EUS-FNA (K180363) by FINEMEDIX Co., Ltd.

5 Device Description:

The ClearTip is a manually operated endoscopic instrument intended to obtain tissue specimens of gastrointestinal tract (=digestive tract) and tracheobronchial tree.
The subject device mainly consists of a handle unit with an insertion part, a syringe, a stopcock, and a connector. This device passes through a working channel of an endoscope, and the average contact time with the submucosal or external lesions of a gastrointestinal tract or a tracheobronchial tree 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 ClearTip is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree and Gastrointestinal Tract, (e.g., lymph nodes, abnormal tissue in the mediastinum).

7 Substantial Equivalence Discussion:

7.1.Comparison Chart

	Subject Device	Primary Predicate	Reference Device
Manufacturer	FINEMEDIX Co., Ltd.	Medi-Globe Corporation	FINEMEDIX Co., Ltd.
Device Name	ClearTip	SonoTip Pro and Pro Flex EBUS-TBNA Needle System	Clear-Tip EUS-FNA
510(k) Number	K231267	K133763	K180363
Device Classification Name	Gastroenterology-urology Biopsy instrument	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-urology Biopsy instrument
Product Code	FCG	FCG	FCG
Regulation Number	21 CFR 876.1075	21 CFR 876.1075	21 CFR 876.01075
Indications for Use	The ClearTip is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree and Gastrointestinal Tract, (e.g., lymph nodes, abnormal tissue in the mediastinum).	The SonoTip Pro and Pro Flex - TBNA Needle System is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree and Gastrointestinal Tract, (e.g., lymph nodes, abnormal tissue in the mediastinum).	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.
Needle Gauge	22 Gauge	22 Gauge	19,22,25 Gauge
Needle Material	Nitinol	Stainless Steel / Nitinol	Stainless Steel
Needle length Adjustment range	0~5 cm	0~4 cm	0~8cm
Stylet Material	Nitinol	Nitinol	Nitinol

Sheath length	738.5 mm	730 mm	1,507 mm
Sheath Material	PEEK, PTFE	PVDF	PEEK
Sheath length Adjustment range	0~3cm	0~4cm	0~5cm
Accessory Channel Diameter	Minimum Accessory Channel Diameter (2.0 mm)	Minimum Accessory Channel Diameter (2.0 mm)	Minimum Accessory Channel Diameter (2.0 mm)
Endoscope Compatibility (Use with connector)	1) Olympus, 2) Pentax	1) Olympus, 2) Pentax	1) Olympus
Use with a Syringe and stopcock	Yes	Yes	Yes
Principle of Operation	Manual (sampling using aspiration)	Manual (sampling using aspiration)	Manual (sampling using aspiration)
Shelf life	3 Years	5 Years	3 Years
Sterility	Ethylene oxide(EO)	Ethylene oxide(EO)	Ethylene oxide(EO)
Single use	Yes	Yes	Yes

7.2. Substantial Equivalence Discussion

The subject device is substantially equivalent to the primary predicate devices in the indications for use, needle gauge, needle material, stylet material, accessory channel diameter, endoscope compatibility, use with a syringe and stopcock, principle of operation, sterility, and single use.

The differences between the subject device and the primary predicate device are as below:

-Needle Length Adjustment Range: The maximum needle length of the subject device is 5 cm, and the predicate device is 4 cm. The difference of 1 cm between the two devices does not affect safety and effectiveness during biopsy. It is just an option for the operator to adjust the length of the needle in consideration of the surgical area (position and depth of the tissue to be biopsied).

-Sheath Length: The sheath length of the subject device is 738.5 mm, and the predicate device is 730 mm. The difference of 8.5 mm does not affect safety and effectiveness during biopsy since the physician can control the length as needed.

-Sheath Material: The raw material of the sheath of the subject device is PEEK & PTFE, and the predicate device is PVDF. We performed biocompatibility testing on the subject device, and based on the test result, we conclude that the subject device is biocompatible and substantially equivalent to the predicate devices.

-Shelf Life: The shelf life of the subject device is 3 years, and the shelf life of the predicate device is 5 years. We performed shelf-life testing, and based on the test result, we conclude that the subject device has 3-year shelf life.

We are presenting Clear-Tip EUS-FNA (K180363) made by our company as a reference device. It shares similarities with the subject device in terms of indications for use statement, needle gauge, stylet material, accessory channel diameter, endoscope compatibility, use with a syringe and stopcock, principle of operation, sterility, and single use.

The differences between the subject device and the reference predicate device are as follows:

- Claim: The reference device does not include a claim on the Tracheobronchial Tree.

- Sheath Length: The sheath of the subject device is shorter than that of the reference device. The shortened length of the subject device is for user convenience, especially when using the device on the Tracheobronchial Tree.

- This reference device is presented to leverage some of the test items, such as EO sterilization validation, Real-Time Shelf-Life, and Shipping Validation, for the subject device. We have also referenced the test parameters, test method, and P/F criteria from this 510k.

8. Non-clinical Tests

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

- Sterilization Validation Test
- Shelf-Life Test
- Appearance
- Dimensions
- Operability
- Elasticity
- Bending Strength
- Pull-out
- Tensile Force
- Biocompatibility Tests

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.