August 21, 2025

FINEMEDIX Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K250994
Trade/Device Name: ClearTip FNA and FNB Types
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: FCG
Dated: July 21, 2025
Received: July 21, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

SIVAKAMI VENKATACHALAM -S

for
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250994

Please provide the device trade name(s).

ClearTip FNA and FNB Types

Please provide your Indications for Use below.

The ClearTip FNA and FNB Types are intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Gastrointestinal Tract, (e.g., lymph nodes, abnormal tissue in the mediastinum).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

(K250994)

July 18, 2025

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

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Email: juhee.c@LKconsultingGroup.com

3. Device Name:

- Trade Name : ClearTip FNA and FNB Types
- Classification : Class II
- Classification Name : Gastroenterology-Urology Biopsy Instrument
- Product Code : FCG
- Regulation Number : 876.1075
- Review Panel : Gastroenterology/Urology

4. Predicate Devices:

- Primary Predicate Device: ClearTip (K231267) by FINEMEDIX Co., Ltd.
- Reference 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). The subject device mainly consists of a handle unit with an insertion part, a syringe, a stopcock, and a connector. ClearTip is offered in various needle gauges for insertion and aspiration. The available needle gauge sizes of 19, 22, and 25 gauge. 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 coil sheath and the needle to enable the user to adjust for the working length of the endoscope and to control 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 gastrointestinal 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 ClearTip FNA and FNB Types are intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the 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.	FINEMEDIX Co., Ltd.	FINEMEDIX Co., Ltd.
Device Name	ClearTip FNA and FNB Types	ClearTip	Clear-Tip EUS-FNA
510(k) Number	K250994	K231267	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 876.1075
Indications for Use	The ClearTip FNA and FNB Types are intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Gastrointestinal Tract, (e.g., lymph nodes, abnormal tissue in the mediastinum).	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 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	19, 22, 25 Gauge	22 Gauge	19, 22, 25 Gauge
Needle Material	Stainless Steel, Nitinol	Nitinol	Stainless Steel
Needle length	0~8 cm	0~5 cm	0~8cm

Adjustment range			
Stylet Material	Nitinol	Nitinol	Nitinol
Sheath length	1,510 mm	738.5 mm	1,507 mm
Sheath Material	Stainless Steel	PEEK, PTFE	PEEK
Sheath length Adjustment range	0~5cm	0~3cm	0~5cm
Accessory Channel Diameter	Minimum Accessory Channel Diameter (2.8 mm)	Minimum Accessory Channel Diameter (2.0 mm)	Minimum Accessory Channel Diameter (2.0 mm)
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	3 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 predicate device in the indications for use and technical characteristics including endoscope compatibility, use with a syringe and stopcock, principle of operation, sterility, and single use.

The differences are in needle gauge, needle length, adjustment range, and sheath length so we identified a reference device (K180363) which encompass the specifications. The sheath material is also different; however, we conducted biocompatibility and performance testing and the test results supports that these differences do not raise a question in safety and effectiveness.

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

- Endoscope Compatibility Test

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.