April 16, 2026

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

Re: K251478
Trade/Device Name: ClearTip TBNA Type
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: March 18, 2026
Received: March 18, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
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DHT1C: Division of Anesthesia,
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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)*
K251478

Device Name
ClearTip TBNA Type

Indications for Use *(Describe)*

The ClearTip TBNA Type is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree.

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

(K251478)

Apr 15, 2026

1. Submitted by:

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2. US Agent/ Official Correspondent:

Priscilla Chung

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3. Device Name:

- Trade Name : ClearTip TBNA Type
- Classification : Class II
- Classification Name : Bronchoscope (Flexible Or Rigid) And Accessories
- Product Code : KTI
- Regulation Number : 874.4680
- Review Panel : Ear Nose & Throat

4. Predicate Devices:

Primary Predicate Device - Single Use Aspiration Needle (K190239) by Olympus Medical Systems Corp.
Reference Device - ClearTip (K231267) by FINEMEDIX Co., Ltd.

5 Device Description:

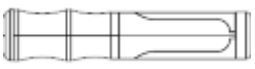
The ClearTip TBNA Type is a manually operated endoscopic instrument intended to obtain tissue specimens of tracheobronchial tree.
The subject device mainly consists of a handle unit with an insertion part, a syringe, a stopcock, and a connector. This device passes through a working channel of an endoscope, and the average contact time with the submucosal or external lesions of a tracheobronchial tree is less than 1 hour. This device is supplied sterile for single-patient use and shall not be reused or re-sterilized.

6 Indications for Use Statement

The ClearTip TBNA Type is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree.

7 Substantial Equivalence Discussion:

7.1. Comparison Chart

	Subject Device	Primary Predicate	Reference Device	Comparison
Manufacturer	FINEMEDIX Co., Ltd.	Olympus Medical Systems Corp.	FINEMEDIX Co., Ltd.	
Device Name	ClearTip TBNA Type	Single Use Aspiration Needle	ClearTip	
510(k) Number	K251478	K190239	K231267	
Device Classification Name	Bronchoscope (Flexible Or Rigid) And Accessories	Bronchoscope (Flexible Or Rigid) And Accessories	Gastroenterology-urology Biopsy instrument	
Product Code	KTI	KTI	FCG	
Regulation Number	21 CFR 874.4680	21 CFR 874.4680	21 CFR 876.1075	
Indications for Use	The ClearTip TBNA Type is intended for Ultrasonically Guided Fine Needle Aspiration, (FNA) of submucosal and extraluminal lesions of the Tracheobronchial Tree.	This instrument has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the Tracheobronchial Tree.	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).	Similar
Handle Design				Slightly different
Needle Gauge	19, 22 Gauge	25 Gauge	22 Gauge	Slightly different
Needle length Adjustment	0~5 cm	2~4 cm	0~5 cm	Similar

range				
Sheath length	746.5 mm, 754.5 mm, 774.5 mm	700 mm	738.5 mm	Slightly different
Total length of the needle	915mm, 935mm, 955mm	-	999mm, 1,005mm.	Slightly different
Patient Contacting Materials Outer Sheath	PEEK, Nitinol, PTFE	Polytetrafluoroethylene, Stainless Steel, Nickel Titanium	PEEK, Nitinol, PTFE	Similar
Sheath length Adjustment range	0~3cm	0~2cm	0~3cm	Similar
Accessory Channel Diameter	Minimum Accessory Channel Diameter (2.2 mm)	Minimum Accessory Channel Diameter (2.0 mm)	Minimum Accessory Channel Diameter (2.0 mm)	Similar
Use with a Syringe and stopcock	Yes	Yes	Yes	Similar
Principle of Operation	Manual (sampling using aspiration)	Manual (sampling using aspiration)	Manual (sampling using aspiration)	Similar
Shelf life	3 Years	3 Years	3 Years	Similar
Sterility	Ethylene oxide(EO)	Ethylene oxide(EO)	Ethylene oxide(EO)	Similar
Single use	Yes	Yes	Yes	Similar

7.2. Substantial Equivalence Discussion

The reference device (unmodified device) manufactured by our company covers the indication for use as the subject device.

The differences between the subject device and the unmodified device are limited to the handle shape, the addition of one additional needle gauge option (19 gauge), the sheath length, and the total needle length. The modified handle design is similar to that of the primary predicate device, K190239.

To evaluate whether these differences affect the safety or effectiveness of the subject device, comparative performance testing was conducted between the subject device and the predicate device. The testing addressed the modified dimensional characteristics. The results demonstrated that the subject device performs comparably to the unmodified device and meets the same acceptance criteria.

Based on the test results, we determine that the subject device is substantially equivalent to the predicate device.

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.

- Appearance

- Dimensions
- Operability
- Elasticity
- Flexural strength
- Pull out
- Tensile force tests
- Insertion and Withdrawal Force
- Needle Extraction/Retraction
- Needle Slider Performance

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.