July 24, 2026

Cook Ireland, Ltd.
Caoimhe Murphy
Official Correspondent
O'Halloran Rd.
National Technology Park, Plassey
Limerick, N/A V94 N8X2
Ireland

Re: K261274
Trade/Device Name: EchoTip Ultra® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes; EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: April 17, 2026
Received: April 17, 2026

Dear Caoimhe Murphy:

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,

John S. Bender -S

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261274

Device Name
EchoTip Ultra® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes
EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes

Indications for Use *(Describe)*
EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes:
This device is used to sample targeted submucosal and extramural lesions within or adjacent to the tracheobronchial tree through the accessory channel of an ultrasound endoscope for fine needle aspiration (FNA).

EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes:
This device is used with an ultrasound endoscope for fine needle biopsy (FNB) of submucosal and extramural lesions within or adjacent to 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K261274

EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes
EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes
21 CFR §876.1075
Date Prepared: 24 July 2026

Submitted By:

Submission:	Traditional 510(k) Premarket Notification- K261274
Applicant:	Cook Ireland Ltd
Applicant Address:	O'Halloran Road
	National Technology Park
	Plassey Limerick V94 N8X2, Ireland
Contact:	Caoimhe Murphy
Email:	Caoimhe.Murphy@CookMedical.com
Contact Phone Number:	+35361334440

Device Information:

Trade Name:	EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes
Device Common Name:	Bronchoscope (flexible or rigid) and Accessories.
Classification Regulation:	21 CFR 874.4680
Product Code:	KTI
Device Classification:	Class II

Predicate Device:
ViziShot 2 FLEX (K193517, Olympus Surgical Technologies America, Gyrus ACMI, Inc.)

Reference Device:
EchoTip Ultra® Endobronchial High-Definition Ultrasound Needle for Olympus Scopes and the EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Olympus Scopes (K210476, Cook Ireland Ltd).

Device Description:
The EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes and the EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes are endoscopic ultrasound needles, available in two different needle sizes (22 and 25 gauge), and contain the following components:

a needle assembly, syringe and an accessory channel adapter for use with the Fujifilm endobronchial ultrasound (EBUS) scope.

Fujifilm EBUS scopes do not have a Luer fitting to allow needle attachment directly to the accessory channel port. The EchoTip Ultra and EchoTip Procore Endobronchial HD Ultrasound Needle for Fujifilm Scopes are supplied with an accessory channel adapter to function as a Luer fitting, to which the needle can be connected. The device is inserted into the scope accessory channel and attached when the fittings meet. The sheath length can be adjusted depending on the length of the EBUS scope using the sliding sheath adjuster. The needle length extension can be adjusted as required. The device is used to puncture the target site to obtain a sample. If using a standard vacuum syringe technique, the stylet is then removed, and the syringe is attached to the Luer fitting on the needle handle. Turning the syringe stopcock to the "open" position allows negative pressure to aspirate the sample. The handle is gently moved in small increments back and forth within the target site to obtain a sample. If using the syringe, the stopcock is returned to the "closed" position. The needle is retracted into the sheath and the device is disconnected from the scope accessory channel. Upon completion of the procedure the adapter is removed from the accessory channel port.
The Adapter Component is the only modification to the reference device, consisting of a colour change and a dimensional modification to the 'Adapter Base' permitting compatibility to the Fujifilm Scope.

Indications for Use:
EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes:
This device is used to sample targeted submucosal and extramural lesions within or adjacent to the tracheobronchial tree through the accessory channel of an ultrasound endoscope for fine needle aspiration (FNA).

EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes:
This device is used with an ultrasound endoscope for fine needle biopsy (FNB) of submucosal and extramural lesions within or adjacent to the tracheobronchial tree .

Technological Comparison:
Both the subject device and the predicate, ViziShot 2 FLEX, has been designed to be used with ultrasound endoscopes, indicated for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree. There are technological similarities and differences between the subject device, EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes and the EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm

Scopes, and the predicate, ViziShot 2 FLEX. Refer to Table 1 for Comparison of Technological Characteristics.

The subject device has the same technological characteristics and design as the reference device, EchoTip Ultra® Endobronchial High-Definition Ultrasound Needle for Olympus Scopes and the EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Olympus Scopes, cleared under K210476 on May 20th, 2021. The Adapter Component is the only design modification to the reference device, which includes a colour change and a dimensional modification to the 'Adapter Base' permitting compatibility to the Fujifilm Scope.

Refer to Table 1 for Comparison of Technological Characteristics:

Parameter	**Subject Device:**	**Predicate Device:**	**Reference Device**	**Comparison**
Device Name	**EchoTip Ultra® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes / EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes**	**ViziShot 2 FLEX**	**EchoTip Ultra® Endobronchial High-Definition Ultrasound Needle EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Olympus Scopes**	
510(k) Number	K261274	K193517	K210476	

Parameter	Subject Device:	Predicate Device:	Reference Device	Comparison
Indications for Use	*EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes:* This device is used to sample targeted submucosal and extramural lesions within or adjacent to the tracheobronchial tree through the accessory channel of an ultrasound endoscope for fine needle aspiration (FNA). *EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes:* This device is used with an ultrasound endoscope for fine needle biopsy (FNB) of submucosal and extramural lesions within or adjacent to the tracheobronchial tree.	The ViziShot 2 FLEX has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the Tracheobronchial tree. Do not use this device for any purpose other than its intended use.	*EchoTip Ultra® Endobronchial HD Ultrasound Needle for Olympus Scopes*: This device is used to sample targeted submucosal and extramural lesions within or adjacent to the tracheobronchial tree or gastrointestinal tract through the accessory channel of an ultrasound endoscope for Fine Needle Aspiration (FNA) *EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Olympus Scopes:* This device is used with an ultrasound endoscope for fine needle biopsy, (FNB), of submucosal and extramural lesions within or adjacent to the tracheobronchial tree or gastrointestinal tract.	Similar to the Predicate device.
FDA Classification Code	KTI	KTI	FCG	Identical to the predicate
Anatomical Sites	Tracheobronchial tree.	Tracheobronchial tree.	Tracheobronchial tree and gastrointestinal tract	Identical to the predicate
Needle Cannula Material	304 Stainless Steel	Unknown	304 Stainless Steel	Identical to the reference device,

Parameter	Subject Device:	Predicate Device:	Reference Device	Comparison
Wire Material	Nitinol	Unknown	Nitinol	K193517 lists combined patient-contacting materials only (Stainless Steel, PTFE, PEBAX, Nitinol)
Needle Gauge	22G, 25G	19G	22G, 25G	Identical to the reference device
Stylet Shape Upon Removal	Straight	Unknown	Straight	Identical to the reference device
Method for Sheath / Needle Adjustment	Handle with a safety ring and sheath adjuster including thumbscrews that enable needle and sheath adjustment. Graduation markers indicate extension.	Lever-lock handle advancement; no sheath adjustment reported	Handle with a safety ring and sheath adjuster including thumbscrews that enable needle and sheath adjustment. Graduation markers indicate extension.	Identical to the reference device
Minimum Compatible Endoscope Channel Size	2.0 mm	2.2 mm	2.0 mm	Identical to the reference device
Supplied with Syringe (with Stopcock)	Yes	Yes	Yes	Identical
Mechanism / Principle of Operation	Manual	Manual	Manual	Identical
Device Usage	For Professional Use	For Professional Use	For Professional Use	Identical
Single Use or Reusable	Single Use	Single Use	Single Use	Identical

Parameter	Subject Device:	Predicate Device:	Reference Device	Comparison
Method of connection to compatible Scope	The EchoTip Ultra and EchoTip Procore Endobronchial HD Ultrasound Needle for Fujifilm Scopes are supplied with an accessory channel adapter to function as a Luer fitting, to which the needle can be connected.	The handle is then affixed to the channel port of the endoscope via a lever mechanism that locks onto the Adapter Biopsy Valve.	The EchoTip Ultra and EchoTip Procore Endobronchial HD Ultrasound Needle for Olympus Scopes are supplied with an accessory channel adapter to function as a Luer fitting, to which the needle can be connected.	Identical to the reference device
Method of Sterilization	EO	EO	EO	Identical
Accessory channel adapter Base color	Black	Unknown	Grey	Different
Scope Compatibility	Fujifilm Scope	Ultrasound Endoscope (Brand not reported)	Olympus Scope	Different
Accessory channel Adapter Base Component	Present	Unknown	Present	The accessory channel adapter base component is Dimensionally Different to the reference device.

Performance Data:

The subject device, EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes and the EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes, is identical to the reference device, EchoTip Ultra® Endobronchial High-Definition Ultrasound Needle for Olympus Scopes and the EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Olympus Scopes (K210476, Cook Ireland Ltd) in all design and technological characteristics except for the Adapter Component, which is the only design modification to the reference device.

Bench testing was conducted on the modified devices to ensure that the devices meet pre-determined acceptance criteria, and to confirm the performance characteristics of the devices. The simulated use testing performed utilised a well-established test method applied to the reference devices cleared under K210476.

Conclusion

All device non-clinical bench test results are acceptable. Data demonstrates that the EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes and the EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes with the modified adapter meets the design specifications and the pre-defined acceptance criteria.

Cook Ireland Ltd. has demonstrate that the subject device, EchoTip Ultra® Endobronchial HD Ultrasound Needle for Fujifilm Scopes and the EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes with the modified adapter is substantially equivalent to the predicate devices and presents no new questions of safety or effectiveness.