July 29, 2024

Cook Ireland Ltd.
Laura O'Reilly
Regulatory Scientist
O'Halloran Road
National Technology Park, Plassey
Limerick, V94 N8X2
Ireland

Re: K241209
Trade/Device Name: EchoTip AcuCore™ EUS Biopsy Needle (ECHO-BX-19)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: FCG
Dated: April 30, 2024
Received: April 30, 2024

Dear Laura O'Reilly:

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.

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241209

Device Name

EchoTip AcuCore™ EUS Biopsy Needle (ECHO-BX-19)

Indications for Use *(Describe)*

This device is used with an ultrasound endoscope for fine needle biopsy (FNB), of submucosal and extramural 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.

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

EchoTip AcuCore™ EUS Biopsy Needle (ECHO-BX-19)
21 CFR §876.1075
Date Prepared: 25 July 2024

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Ireland Ltd
Applicant Address:	O'Halloran Road National Technology Park Plassey Limerick V94 N8X2, Ireland
Contact:	Brian O'Mara
Email:	brian.omara@cookmedical.com
Contact Phone Number:	+35361334440

Device Information:

Trade Name:	**EchoTip AcuCore™ EUS Biopsy Needle (ECHO-BX-19)**
Common Name:	Gastroenterology-urology biopsy instrument
Classification Regulation:	21 CFR §876.1075
Product Class:	Class II
Product Code:	FCG
Panel:	Gastroenterology/Urology

Predicate Device:

Primary Predicate: EchoTip AcuCore™ EUS Biopsy Needle (K230909, Cook Ireland Ltd)

Reference Predicate: EchoTip ProCore® HD Ultrasound Biopsy Needle (K210476, Cook Ireland Ltd)

Device Description:

The EchoTip AcuCore™ EUS Biopsy Needle (ECHO-BX-19) is an endoscopic ultrasound needle consisting of a needle assembly and syringe. The needle assembly is comprised of a handle, sheath, stylet and needle cannula. This device will be available in a 19Ga needle size. The EchoTip AcuCore™ EUS Biopsy Needle is currently available in a 22Ga needle cleared by the FDA under K230909. The device is indicated for ultrasound guided tissue sampling of submucosal and extramural lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the gastrointestinal tract, which is used for subsequent pathological examination to aid in disease diagnosis and patient management.

Intended use / Indications for Use:

This device is used with an ultrasound endoscope for fine needle biopsy (FNB), of submucosal and extramural lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the gastrointestinal tract.

Technological Comparison:

The subject device is substantially equivalent to the currently marketed device, EchoTip AcuCore™ EUS Biopsy Needle (ECHO-BX-3-22), cleared under K230909 on May 30th, 2023. In brief, the subject device is identical to the predicate device with regard to the following:

- Needle material
- Needle length extension range
- Needle Tip Design
- Stylet wire material
- Sheath length extension range
- Handle (method of needle and sheath adjustment)
- Endoscope compatibility
- Syringe
- Shelf life
- Sterility (Ethylene oxide, EO)
- For single use
- For professional use
- Principle of operation

The following technological differences exist between the modified devices and the currently marketed predicate devices:

- Needle Gauge
- Sheath Material & Dimension
- Stylet Tip Design
- Number of Dimples on Needle
- Stylet Shape upon Removal
- Needle Strain Relief

Performance Data:

The EchoTip AcuCore™ EUS Biopsy Needle (ECHO-BX-19) is determined to be substantially equivalent to the predicate device. Non-clinical testing was performed to support substantial equivalence with the predicate device. Various bench tests were included in the performance data, including: Needle Crumpling Compression test, Suction test, Needle Extension Length test, Stylet pull test, Simulated use testing, Biocompatibility testing and Sterilization testing.

Conclusion

The non-clinical data confirms that the 19Ga EchoTip AcuCore™ EUS Biopsy Needle meets the design input requirements based on the intended use and supports the conclusion that this device does not raise new questions of safety and/or effectiveness and is substantially equivalent to the predicate device, the 22Ga EchoTip AcuCore™ EUS Biopsy Needle (K230909, Cook Ireland Ltd).