May 20, 2021

Cook Ireland Ltd.
Jane Kennedy
Senior Regulatory Affairs Specialist
O'Halloran Road, National Technology Park
Limerick, Ireland

Re: K210476
Trade/Device Name: EchoTip Ultra Endoscopic Ultrasound Needle, EchoTip ProCore HD Ultrasound Biopsy Needle, EchoTip Ultra Endobronchial High Definition Ultrasound Needle, EchoTip ProCore Endobronchial High Definition Ultrasound Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: FCG
Dated: February 12, 2021
Received: February 19, 2021

Dear Jane Kennedy:

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, 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)*
K210476

Device Name
Echotip® Ultra Endoscopic Ultrasound Needle, Echotip Procore® HD Ultrasound Biopsy Needle
Echotip® Ultra Endobronchial High Definition Ultrasound Needle
Echotip Procore® Endobronchial High Definition Ultrasound Biopsy Needle

Indications for Use *(Describe)*
The EchoTip® Ultra Endoscopic Ultrasound Needle is used with an ultrasound endoscope for fine needle aspiration (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.

The EchoTip ProCore® HD Ultrasound Biopsy Needle is used with an ultrasound endoscope for fine needle biopsy (FNB), of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.

Echotip® Ultra Endobronchial High Definition 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® Ultra Endobronchial High Definition Ultrasound Needle for Pentax 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 High Definition 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.

Echotip Procore® Endobronchial High Definition Ultrasound Biopsy Needle for Pentax 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.

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510(k) Summary

I. SUBMITTER

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Date Prepared: February 12th, 2021

II. DEVICE

Trade Name of Device: EchoTip Ultra Endoscopic Ultrasound Needle
The model numbers are ECHO-19, ECHO-1-22, and ECHO-25.
Common or Usual Name: Endoscopic Ultrasound Needle (Biopsy Needle Kit)
Classification Name: Gastroenterology/Urology (21 CFR 876.1075)
Regulatory Class: II
Product Code: FCG

Trade Name of Device: EchoTip ProCore HD Ultrasound Biopsy Needle
The model numbers are ECHO-HD-19-C, ECHO-HD-3-20-C, ECHO-HD-22-C, and ECHO-HD-25-C.
Common or Usual Name: Endoscopic Ultrasound Needle (Biopsy Needle Kit)
Classification Name: Gastroenterology/Urology (21 CFR 876.1075)
Regulatory Class: II
Product Code: FCG

Trade Name of Device: EchoTip Ultra Endobronchial High Definition Ultrasound Needle
The model numbers are ECHO-HD-22-EBUS-O, ECHO-HD-22-EBUS-P, ECHO-HD-25-EBUS-O, and ECHO-HD-25-EBUS-P.
(O = for use with Olympus scope, P = for use with Pentax scope)
Common or Usual Name: Endoscopic Ultrasound Needle (Biopsy Needle Kit)
Classification Name: Gastroenterology/Urology (21 CFR 876.1075)
Regulatory Class: II
Product Code: FCG

Trade Name of Device: EchoTip ProCore Endobronchial High Definition Ultrasound Biopsy Needle
The model numbers are ECHO-HD-22-EBUS-O-C, ECHO-HD-22-EBUS-P-C, ECHO-HD-25-EBUS-O-C, and ECHO-HD-25-EBUS-P-C.
(O = for use with Olympus scope, P = for use with Pentax scope)
Common or Usual Name: Endoscopic Ultrasound Needle (Biopsy Needle Kit)
Classification Name: Gastroenterology/Urology (21 CFR 876.1075)
Regulatory Class: II
Product Code: FCG

III. PREDICATE DEVICE

Endoscopic Ultrasound Needle, K083330 cleared on February 6th, 2009.
EchoTip ProCore HD Ultrasound Biopsy Needle, K142688 cleared on December 19th, 2014.
EchoTip Ultra / ProCore Endobronchial High Definition Ultrasound Needle, K160229 cleared on March 21st, 2016.

The predicate devices detailed above have never been subject to a design related recall.

IV. DEVICE DESCRIPTION

EchoTip Ultra Endoscopic Ultrasound Needle

This Needle is used in conjunction with an ultrasound endoscope and is available in needle gauge sizes of 19, 22 and 25 Ga. The device comprises of a needle assembly and a syringe. The needle assembly consists of the needle cannula, stylet, sheath and handle. The stainless steel needle cannula has a dimpling pattern on the distal end to allow visualization of the needle tip under endoscopic ultrasound. The purpose of the needle cannula is for puncturing of the target site. The preloaded nitinol stylet is withdrawn from the needle when obtaining sample from the target site. The sheath covers the needle when it is not in use. The device handle allows for needle and sheath length adjustment. The syringe can aid in sample aspiration. The device is supplied sterile and is intended for single use. The device is for Rx use only.

EchoTip ProCore HD Ultrasound Biopsy Needle

This Needle is used in conjunction with an ultrasound endoscope and is available in needle gauge sizes of 19, 20, 22 and 25 ga. The device comprises of a needle assembly and a syringe. The needle assembly consists of the needle cannula, stylet, sheath and handle. The stainless steel needle cannula has a dimpling pattern on the distal end to allow visualization of the needle tip under endoscopic ultrasound. The needle cannula has a bevelled tip design and a notch. The purpose of the needle cannula is for puncturing/biopsy of the target site. The preloaded nitinol stylet is withdrawn from the needle for biopsy. Some variants have a stylet that coils when not in the needle. The sheath covers the needle when it is not in use. The device handle allows for needle and sheath length adjustment. The syringe can aid in tissue aspiration. The device is supplied sterile and is intended for single use. The device is for Rx use only.

EchoTip Ultra / ProCore Endobronchial High Definition Ultrasound Needle

These Needles are used in conjunction with an endobronchial ultrasound endoscope and is available with needle gauge sizes of 22 and 25 Ga. The device is composed of a needle assembly and a syringe. An adapter can also be supplied for use with endobronchial ultrasound endoscopes with metal non-Luer hubs. The needle assembly consists of the needle cannula, stylet, sheath and handle. The stainless steel needle cannula has a dimpling pattern on the distal end to allow visualization of the needle tip under endoscopic ultrasound. The needle cannula has a bevelled tip design and comes either with or without a notch. The purpose of the needle cannula is for puncturing/sampling of the target site. The needle is provided with a preloaded stylet which remains in place during advancement of the needle. The sheath covers the needle when the needle is retracted and not in use. The device handle allows for needle and sheath length adjustment. The stylet/syringe can aid in specimen retrieval. The device is supplied sterile and intended for single use only. The device is for Rx use only.

V. INDICATIONS FOR USE

Subject Device	**Predicate Device**
The EchoTip Ultra Endoscopic Ultrasound Needle is used with an ultrasound endoscope for fine needle aspiration (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.	**EchoTip Ultra Ultrasound Needle (K08333):** This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues during endoscopic procedures and fine needle aspiration (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract. There were no new risks introduced as the intended use of the subject device falls within the broader intended use of the predicate device cleared under K083330.
The EchoTip ProCore HD Ultrasound Biopsy Needle is used with an ultrasound endoscope for fine needle biopsy (FNB), of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract.	**Unchanged from EchoTip ProCore HD Ultrasound Biopsy Needle, K142688.**

Subject Device	Predicate Device
Echotip® Ultra Endobronchial High Definition 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).	**Unchanged from EchoTip Ultra Endobronchial High Definition Ultrasound Needle, K160229.**
Echotip® Ultra Endobronchial High Definition Ultrasound Needle for Pentax 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).	**Unchanged from EchoTip Ultra Endobronchial High Definition Ultrasound Needle, K160229.**
Echotip Procore® Endobronchial High Definition 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.	**Unchanged from EchoTip ProCore Endobronchial High Definition Ultrasound Needle, K160229.**
Echotip Procore® Endobronchial High Definition Ultrasound Biopsy Needle for Pentax 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.	**Unchanged from EchoTip ProCore Endobronchial High Definition Ultrasound Needle, K160229.**

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The modified devices are substantially equivalent to the currently marketed predicate devices, the Endoscopic Ultrasound Needle, K083330 cleared on February 6th, 2009, the EchoTip ProCore HD Ultrasound Biopsy Needle, K142688 cleared on December 19th, 2014 and the EchoTip Ultra / ProCore Endobronchial High Definition Ultrasound Needle, K160229 cleared on March 21st, 2016.

In brief, the modified devices are identical to their respective predicate devices with regard to the following:

- Needle gauge size
- Needle material
- Needle length extension range
- Stylet wire material
- Sheath length extension range
- Sheath material
- 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:

- Dimensional changes to inner components of the handle.
- EchoTip Ultra / ProCore Endobronchial High Definition Ultrasound Needle: Dimensional change to the Female Luer Lock Adaptor (FLLA) connector on the Olympus Adaptor.
- EchoTip Ultra Endoscopic Ultrasound Needle: The stylet distal tip for the 22 Ga needle is changed from a bevelled tip to a ball tip and the stylet wire for the 19 Ga and 22 Ga needles are slightly reduced.

These differences in technological characteristics do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

A biocompatibility evaluation for the proposed modifications was conducted in accordance with the FDA guidance document Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" issued on September 4, 2020 and the International Standard ISO 10993-1: 2018 "Biological evaluation of medical devices − Part 1: Evaluation and testing within a risk management process," as recognised by FDA.

The device specific guidance document was consulted in preparing this premarket submission, *Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology.*
Performance testing was performed as per Cook Ireland's design control system; the following tests were conducted:

- Tensile testing
- Crumple testing
- Joint strength testing
- Finite element analysis
- Simulated use and drop testing

VIII. CONCLUSIONS

The non-clinical data supports the safety of the modified devices and demonstrates that the EchoTip Ultra Endoscopic Ultrasound Needle, the EchoTip ProCore HD Ultrasound Biopsy Needle and the EchoTip Ultra / ProCore Endobronchial High Definition Ultrasound Needle is safe and effective and should perform as intended in the specified use conditions. This non-clinical data supports the substantial equivalence of the EchoTip Ultra Endoscopic Ultrasound Needle, the EchoTip ProCore HD Ultrasound Biopsy Needle and the EchoTip Ultra / ProCore Endobronchial High Definition Ultrasound Needle to their respective predicate devices.