May 30, 2023

Cook Ireland Ltd.
% Paul Meyer
Regulatory Scientist
Cook Medical
750 Daniels Way
Bloomington, IN 47404

Re: K230909
Trade/Device Name: EchoTip® AcuCore™ Ultrasound Biopsy Needle (ECHO-BX-3-22)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: FCG, ODG
Dated: March 31, 2023
Received: March 31, 2023

Dear Paul Meyer:

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 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230909

Device Name
EchoTip@ AcuCore T M Ultrasound Biopsy Needle (ECHO-BX-3-22)

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 GI 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.

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510(k) Summary

EchoTip® AcuCore™ Ultrasound Biopsy Needle
21 CFR §876.1075
Date Prepared: 19 May 2023

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:	Laura O'Reilly
Email:	laura.oreilly@cookmedical.com
Contact Phone Number:	+35361334440

Device Information:

Trade Name:	**EchoTip® AcuCore™ Ultrasound Biopsy Needle**
Device Common Name:	Gastrointestinal tube and accessories
Classification Regulation:	21 CFR §876.1075, Product Code FCG
Device Class:	Class II
Classification Panel:	Gastroenterology/Urology

Predicate Device:

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

Reference Device: Acquire Endoscopic Ultrasound Needle Biopsy (FNB) Device (Boston Scientific, K160845)

Device Description:

The EchoTip® AcuCore™ Ultrasound Biopsy Needle (ECHO-BX-3-22) 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 is available in one 22Ga needle size. Please see attachment for full device description.

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 GI tract.

Technological Comparison:

A comparison of the features of the subject device, EchoTip® AcuCore™ Ultrasound Biopsy Needle, and the predicate device, EchoTip® ProCore HD Ultrasound Biopsy Needle are presented in Table 1.1 below.

Table 1.1: Substantial Equivalence Comparison.

Parameter	**Comparison**		
Device Name	**Predicate Device:** **EchoTip® ProCore HD Ultrasound Biopsy Needle**	**Subject Device:** **EchoTip® AcuCore™ Ultrasound Biopsy Needle**	**Reference Device:** **Boston Scientific Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device**
Manufacturer	Cook Ireland Ltd.	Identical to predicate	Boston Scientific
Regulation Number	21 CFR 876.1075	Identical to predicate	Identical to predicate
Product Code	FCG	Identical to predicate	ODG, FCG
Classification Name	Gastroenterology - Urology biopsy instrument	Identical to predicate	Identical to predicate
Device Class	II	Identical to predicate	Identical to predicate
Submission	K210476	K230909	K160845
Indications for Use	This device 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.	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 GI tract.	The Acquire™ Fine Needle Biopsy Device is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope.
Needle Cannula:			

Parameter	**Comparison**		
Device Name	**Predicate Device:** **EchoTip® ProCore HD Ultrasound Biopsy Needle**	**Subject Device:** **EchoTip® AcuCore™ Ultrasound Biopsy Needle**	**Reference Device:** **Boston Scientific Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device**
Needle Gauge	19 Ga, 20 Ga, 22 Ga, 25 Ga	22 Ga, Identical to predicate	22 Ga, 25 Ga
Needle Material Composition	Stainless steel	**Cobalt chromium**	**Cobalt chromium**
Needle Length Extension Range	0-8cm	Identical to predicate	Unknown
Needle Tip Bevel	Lancet	**Franseen**	**Franseen**
Side bevel feature	Present	**Not present**	**Not present**
Luer material	Nickel-plate brass	**ABS**	Unknown
Strain Relief	Yes	Identical to predicate	Unknown
Stylet:			
Wire Material	Nitinol	Identical to predicate	Unknown
Needle stylet tip type	Ball	Identical to predicate	Unknown
Stylet Shape Upon Removal	19 Ga, 22 Ga, 25 Ga: Straight 20 Ga: Coiled	Coiled	Unknown
Total number of dimples	19 Ga: 735 ± 2220 Ga: 735 ± 22 22 Ga: 1444 ± 43 25 Ga: 912 +/- 27	22 Ga: 1444 ± 43	None
Sheath:			

Parameter	**Comparison**		
Device Name	**Predicate Device:** **EchoTip® ProCore HD Ultrasound Biopsy Needle**	**Subject Device:** **EchoTip® AcuCore™ Ultrasound Biopsy Needle**	**Reference Device:** **Boston Scientific Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device**
Sheath Outer Diameter (Fr) at Largest Point	19 Ga: 4.8 Fr 20 Ga: 7.95 Fr 22 Ga: 5.2 Fr 25 Ga: 5.2 Fr	**5.3 Fr**	Unknown
Sheath Length Extension Range	0 - 5 cm, adjustable	Identical to predicate	Unknown
Sheath Material	19 Ga, 22 Ga, 25 Ga: Grey Polyetheretherketone (PEEK) 20 Ga: Polytetrafluoroethylene (PTFE) covered stainless steel coil spring sheath with nylon covering.	**Polytetrafluoroethylene (PTFE) coated 304 Stainless Steel (SS) coiled sheath**	Unknown
Adaptor	MLLA	Identical to predicate	Unknown
Handle:			
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.	Identical to predicate	Unknown
Sheath Adjuster	Yes	Identical to predicate	Unknown
Other:			
Minimum Endoscope Channel	19, 22, 25 Ga: 2.8 mm	2.8 mm	Unknown

Parameter	Comparison		
Device Name	**Predicate Device:** **EchoTip® ProCore HD Ultrasound Biopsy Needle**	**Subject Device:** **EchoTip® AcuCore™ Ultrasound Biopsy Needle**	**Reference Device:** **Boston Scientific Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device**
Size Compatibility	20 Ga: 3.7 mm	Identical to same gauge size of predicate device.	
Supplied with Syringe (with Stopcock)	Yes	Identical to predicate	Unknown
Principle/Mechanism of Operation	Manual	Identical to predicate	Identical to predicate
Device Usage	For Professional Use	Identical to predicate	Identical to predicate
Single Use or Reusable	Single Use	Identical to predicate	Identical to predicate
Method of Sterilization	EO	Identical to predicate	Unknown
Patient contact type	Directly patient contacting	Identical to predicate	Identical to predicate
Packaging	Product placed in tray with Tyvek Lidstock	Identical to predicate	Unknown
Shelf Life	3 years	**1 year**	Unknown

The subject EchoTip® AcuCore™ Ultrasound Biopsy Needle shares many design features with the predicate EchoTip ProCore® HD Ultrasound Biopsy Needle, however, there are some differences. The differences between the subject and predicate device are described below.

1. **Change to Intended Use statement:**

The Intended Use of the EchoTip® AcuCore™ Ultrasound Biopsy Needle device will differ in indications from the existing EchoTip ProCore® HD Ultrasound Biopsy Needle devices. Changes to Intended use statement will be from:

"This device 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 GI tract."

to:

"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 GI tract."

This change involves the addition of extramural lesions as an anatomical site, referring to lesions that have originated from outside of the gastrointestinal wall. The objective of this change is to align with the market standard of fine biopsy needle devices used with ultrasound endoscopes, for example Boston Scientifics "Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device" which includes extramural gastrointestinal lesions within the intended use: "The Acquire Fine Needle Biopsy Device is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope."

This change increases clarity around appropriate relevant anatomical sites by acknowledging that the extramural anatomical site is within the scope of sites that a FNB needle is used to biopsy and aligns the EchoTip® AcuCore™ Ultrasound Biopsy Needle device with the state-of-the-art intended use for this device type and intended use. This update to the indications of use falls within the intended use of the predicate EchoTip ProCore® HD Ultrasound Biopsy Needle. Impact assessment of the change as per the Cook Ireland quality system did not identify new risks to procedural steps. The performed Needle Puncture Test supports this indication update by demonstrating the ability to puncture beyond the walls of the GI tract by using a worst case material representative of liver and pancreatic tissue. The addition of the extramural anatomical site does not raise any new concerns regarding the safety and effectiveness of the use or performance of the modified device when compared to that of the predicate. Therefore, this difference does not constitute a new intended use and does not raise any new questions of safety or effectiveness.

2. Needle Material Difference from Stainless Steel to Cobalt chromium

The Boston Scientific Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device also contains a three-point tipped cobalt chromium needle. This device has the same directly patient contacting needle material as the subject device, with a similar nature and duration of patient contact, and similar intended use, and was cleared by the FDA under K160845 on 03 May 2016.

The key benefits delivered by the cobalt chromium biopsy needle are the ability of the component to incorporate a very thin wall while maintaining column strength, kink resistance, and pushability as well as sharpness retention.

Based on the testing carried out within Cook that indicates that there is no new risk associated with cobalt for the use condition when compared to the predicate material, and the supporting literature which proves that the benefits outweigh that of the risk associated with the use of cobalt in medical devices, there is no reason to source an alternative material and the use of cobalt chromium containing cobalt within the device is acceptable. Therefore, the difference in material does not raise any new questions of safety or effectiveness.

3. **Needle tip and side bevel**

The needle tip of the predicate device will have a Franseen instead of a Lancet tip design. The Boston Scientific Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device also contains a three-point tipped Franseen design cobalt chromium needle. This device has the same directly patient contacting needle material as the subject device, with a similar nature and duration of patient contact, and similar intended use, and was cleared by the FDA under K160845 on 03 May 2016.

Fine needle biopsy (FNB) has been introduced in to obtain samples with preserved tissue architecture. Common FNB needle designs include reverse bevel needle, fork-tip needle and Franseen-type needle. One of the most recent introduced FNB needles mentioned above, three-pronged cutting edges Franseen geometry needle, has been reported to acquire a high rate of histological core tissue sampling. Additionally, the bleeding complication rate associated with Franseen needle tip on Pancreas and liver biopsy is comparable with the overall bleeding complication rate using a fine needle aspiration (FNA)/FNB needle on pancreas and liver biopsy. Furthermore, the subject device's capability to perform as intended has been demonstrated through performance testing. Therefore, no new risks or concerns relating to safety and effectiveness of the subject device were raised by making the proposed needle tip design change, when compared to the currently marketed predicate device.

4. **Luer material**

The predicate EchoTip® ProCore HD Ultrasound Biopsy Needles' luer lock is composed of nickel-plated brass whereas the subject EchoTip® AcuCore™ Ultrasound Biopsy Needle's Luer lock is made of Acrylonitrile Butadiene Styrene (ABS). The process for creating the Luer attachment to the needle cannula is also proposed to change from soldering to overmolding. The Luer component is located on the proximal end of device and so, does not directly or indirectly

contact the patient. Nevertheless, biocompatibility and performance testing on the device has demonstrated that the subject device meets the clinically relevant requirements. This difference does not significantly affect the use of the device and there were no new or significantly modified risks identified in the impact assessment of this change. Therefore, the difference in Luer material do not raise any new questions of safety or effectiveness.

5. Sheath material and dimensional difference

The sheath holder assembly components of the predicate devices consist of a Polyetheretherketone (PEEK) tubing component in the 19 Ga, 22 Ga, 25 Ga sizes of the predicate device and a Polytetrafluoroethylene (PTFE) covered stainless steel coil spring sheath with nylon covering in the 20 Ga size of the predicate device. The subject device sheath holder assembly consists of a Polytetrafluoroethylene (PTFE) coated 304 stainless steel (SS) coiled sheath. The PTFE material is comparable and equivalent between the predicate and subject devices in terms of patient contacting material and patient contact type and duration. A biocompatibility assessment and biological testing supports the biological safety of the subject device when used as intended. Additionally, the subject device's capability to perform as intended has been demonstrated through performance testing. Therefore, this material change does not raise any risks or concerns relating to safety or effectiveness for the subject device. The sheath outer diameter (OD) of the modified device is 5.3Fr, the sheath OD for the same needle gauge size (22 Ga) of the predicate device is 5.2Fr. This change has been assessed as non-significant and does not raise new concerns related to safety or effectiveness when considering the subject device.

6. Stylet Style

The stylet of the subject 22 Ga EchoTip® AcuCore™ Ultrasound Biopsy Needle is a recoil stylet, whereas the predicate device's 22 Ga model has a straight stylet. The coiled shape of the stylet allows for easier management of the stylet on removal and reduces risk of contamination. The coiled shape of the subject device is already used in the 20 Ga size of the predicate device and the function of the stylet has been evaluated via performance testing and found to meet the relevant acceptance criteria. Therefore, this difference between the subject and predicate device does not raise any new questions of safety or effectiveness.

7. Shelf life

The shelf life of the modified device will be 1 year (the predicate device shelf life is 3 years). Simulated Use testing has been carried out on 13 months Accelerated Aged devices. This testing supports a 1-year shelf life for the subject device, which falls within the 3-year shelf life of the

predicate device and, therefore, does not raise any concerns or questions regarding subject device safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following non-clinical testing was performed on the subject device to support this submission.

- Needle Crumpling Compression test intended to challenge the ability of the ECHO family of Endoscopic Ultrasound needles to withstand handle angulation. All test articles met the acceptance criteria.
- Suction Test intended to assess the ability of the performance of the device to meet the requirement to perform suction at endoscopic ultrasound needle device based on the suction pressure created by the syringe. All test articles met the acceptance criteria.
- Needle Puncture Test intended to evaluate the comparative performance and function of Endoscopic ultrasound needles in terms of puncture force. All test articles met the acceptance criteria.
- Needle Extension Length test intended to assess the performance of the device to meet the needle extension length test. All test articles met the acceptance criteria.
- Stylet pull test intended to evaluate the removal force for the device's stylet. All test articles met the acceptance criteria.
- Simulated use testing intended to qualitatively evaluate the performance of the device using a tortuous path that simulates the intended use conditions. All acceptance criteria as defined in the study protocol were met.

The results of these tests confirm that the EchoTip® AcuCore™ Ultrasound Biopsy Needle meets the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety and/or effectiveness and is substantially equivalent to the predicate device, the EchoTip ProCore® HD Ultrasound Biopsy Needle (K210476, Cook Ireland Ltd).