DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 21, 2016

Cook Ireland Ltd.
Lynsey Shine
Regulatory Affairs Specialist
O' Halloran Road, National Technology Park
Limerick, Ireland

Re: K160229
Trade/Device Name: 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: January 28, 2016
Received: February 1, 2016

Dear Lynsey Shine,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160229

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

Indications for Use *(Describe)*

Echotip® Ultra Endobronchial High Definition Ultrasound Needle for use with Olympus EBUS 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 use with Pentax EBUS 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 use with Olympus EBUS 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 use with Pentax EBUS 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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Section 5: 510(k) Summary

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Date Prepared: March 16, 2016

II. DEVICE

Trade Name of Device: Echotip® Ultra Endobronchial High Definition Ultrasound Needle and Echotip Procore® Endobronchial High Definition Ultrasound Biopsy Needle.
The model numbers are ECHO-HD-XX-EBUS-X(-C), where XX denotes the needle gauge size, X denotes the type of endobronchial ultrasound endoscope and -C denotes if it is the Procore version of the device.

Model numbers:

ECHO-HD-22-EBUS-O
ECHO-HD-22-EBUS-P
ECHO-HD-25-EBUS-O
ECHO-HD-25-EBUS-P
ECHO-HD-22-EBUS-O-C
ECHO-HD-22-EBUS-P-C
ECHO-HD-25-EBUS-O-C
ECHO-HD-25-EBUS-P-C

Common or Usual Name: Endoscopic Ultrasound Needle (Biopsy Needle Kit)

Classification Name: Gastroenterology-urology biopsy instrument (21 CFR 876.1075)

Regulatory Class: II

Product Code: FCG

III. PREDICATE DEVICE

Echotip® Ultra Endobronchial High Definition Ultrasound Needle, K093195 cleared January 21, 2010.
Echotip Procore® High Definition Ultrasound Biopsy Needle, K142688 cleared December 19, 2014.
None of the predicate devices detailed above have been subject to a design related recall.

IV. DEVICE DESCRIPTION

The Echotip Ultra/ Procore Endobronchial High Definition Ultrasound Needle is 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 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 an additional cutting surface on the distal end of the needle cannula. 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, intended for single use only and is available for prescription use only. Use of this device is restricted to a trained healthcare professional.

V. INDICATIONS FOR USE

Echotip® Ultra Endobronchial High Definition Ultrasound Needle for use with Olympus EBUS 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 use with Pentax EBUS 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 use with Olympus EBUS 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 use with Pentax EBUS 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 predicate Echotip Procore® High Definition Ultrasound Biopsy Needle is indicated for use 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. The Indications for Use statement for the predicate Echotip Procore® High Definition Ultrasound Biopsy Needle device is not identical to the subject device. However, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for Fine Needle Aspiration/ Biopsy within or adjacent to the gastrointestinal tract.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed devices, the Echotip® Ultra Endobronchial High Definition Ultrasound Needle, cleared under K093195 on January 21, 2010 and the Echotip Procore® High Definition Ultrasound Biopsy Needle, cleared under K142688 December 19, 2014. The subject and predicate devices operate in the same manner to obtain a specimen using an ultrasound endoscope.

In brief, the subject device is identical to/ within the range of the Echotip® Ultra Endobronchial High Definition Ultrasound Needle, K093195, primary predicate device, and the Echotip Procore® High Definition Ultrasound Biopsy Needle, K142688, with respect to the following:

- Needle gauge size, material, additional cutting surface on the needle cannula,
- Needle length extension and sheath length extension range of adjustment, method of adjustment for needle and sheath,
- Sheath material and colour,
- Stylet wire material, diameter, distal tip options,
- Compatibility with an endobronchial ultrasound endoscope,
- Supplied with a syringe,
- Principle of operation,
- For professional use,
- For single use,
- Sterility (Ethylene oxide, EO),
- Compatibility with endobronchial ultrasound endoscopes with metal non-Luer hubs (with an adapter),
- Compatibility with ultrasound endoscopes with metal Luer hubs,
- Same endoscope minimum accessory channel size.

The following technological differences exist between the subject device and the Echotip® Ultra Endobronchial High Definition Ultrasound Needle, K093195, primary predicate device, and the Echotip Procore® High Definition Ultrasound Biopsy Needle, K142688, with respect to the following:

- Sheath diameter,
- Detachable sheath adjuster for scopes with a metal Luer hub,
- Compatibility with endobronchial ultrasound endoscopes with metal Luer hubs (no adapter required).

VII. PERFORMANCE DATA

The biocompatibility evaluation for the Echotip Ultra/ Procore Endobronchial High Definition Ultrasound Needle was conducted in accordance with *ISO 10993-1: 2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"* and FDA's biocompatibility guidance, *G95-1 Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (May 1, 1995).*

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 such as dimensional and visual inspections, stylet removal force testing, simulated use testing, device aspiration testing, endoscope evaluation and leak testing, and joint strength testing were performed as per Cook's design control system.

VIII. CONCLUSIONS

The non-clinical data supports the safety of the subject device and demonstrates that 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/ Procore Endobronchial High Definition Ultrasound Needle to the predicate devices.