April 26, 2018

Covidien LLC
Rachel Silva
Principal Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K180037
Trade/Device Name: Beacon EUS Access System
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: March 14, 2018
Received: March 15, 2018

Dear Rachel Silva:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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)*
K180037

Device Name
Beacon EUS Access System

Indications for Use *(Describe)*
The Beacon EUS Access System is used to access the following areas of the gastrointestinal tract: the intra- or extra-hepatic bile ducts, pancreatic ducts, cystic duct, gallbladder or for delivery of injectable materials into tissues through the accessory channel of an ultrasound endoscope.

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.

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510(k) Summary

Submitter's Name and Address:
Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact Person:
Rachel Silva
Principle Regulatory Affairs Specialist
Phone: (408) 328-7359
Fax: (408) 328-7359

Date Prepared: January 3, 2018

Name of Device:
Proprietary Name: Beacon™ EUS Access System
Common/Usual Name: Gastroenterology-urology biopsy instrument
Classification Panel: Gastroenterology/Urology
Device Regulation: 21 CFR 876.1075, Class II
Product Code: FCG

Establishment Registration Number, Owner/Operator Number:
Establishment Registration Number: 3004904811
Owner/Operator Number: 1282497

Predicate Devices:
K142198 BNX FNA System by Covidien llc
K092359 EchoTip Ultra HD Ultrasound Access Needle by Cook Ireland Ltd

Device Description:
The Beacon™ EUS Access System is a sterile, single-use, endoscopic ultrasound device which consists of the Beacon Endoscopic Ultrasound (EUS) Delivery System and a Beacon EUS Access Needle. The Beacon EUS Delivery System with Beacon EUS Access Needle is inserted through the accessory channel of an ultrasound endoscope. The Beacon EUS Access Needle is intended to pierce tissue and then act as an access channel to facilitate guidewire placement to locations of the gastrointestinal tract.

Indications for Use:
The Beacon EUS Access System is used to access the following areas of the gastrointestinal tract: the intra- or extra-hepatic bile ducts, pancreatic ducts, cystic duct, gallbladder or for delivery of injectable materials into tissues through the accessory channel of an ultrasound endoscope.

Technological Characteristics of the Device Compared to Predicate Devices
The subject device has many of the same technological characteristics as the predicate devices. All devices are sterile, single-use, manual devices used in the gastrointestinal tract. The devices are designed to be used through the accessory channel of an ultrasound endoscope and mount to the endoscope via a metal luer adapter located on the handle. All devices have delivery system handles with a series of slidable sub-sections and a catheter sheath. All device systems have metallic removable sharp needles or stylets that pierce tissue.

The primary difference in technological characteristics of the subject device from the predicate devices is the pre-curved design of the removable Beacon EUS Access Needle. The Beacon EUS Access Needle consists of a pre-curved cannula and sharp stylet. Once the stylet is removed from the cannula it takes on a curved shape.

Performance Data
Performance testing for the Beacon™ EUS Access System consisted of in-vitro functional testing, biocompatibility testing, sterilization validation, packaging validation, and shelf life testing. Testing performed demonstrates that the subject device is substantially equivalent to the predicate devices for the proposed intended use.

Conclusion
Covidien llc considers the Beacon™ EUS Access System to be substantially equivalent to the legally marketed predicate devices BNX FNA System (K142198) and EchoTip Ultra HD Access Needle (K092359). Test results and compliance to applicable standards provided in this premarket notification establishes that similarly designed legally marketed devices have been used for the same clinical application.