DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 21, 2017

Covidien, LLC
Ms. Leeanne Swiridow
Sr. Regulatory Affairs Specialist
161 Cheshire Lane, Suite 100
Plymouth, Minnesota 55441

Re: K163537
Trade/Device Name: Arcpoint™ Pulmonary Needle
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 21, 2017
Received: March 22, 2017

Dear Ms. Swiridow:

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*

Device Name
Arcpoint™ pulmonary needle

Indications for Use *(Describe)*
The Arcpoint™ pulmonary needle is utilized through a flexible endoscope or with the superDimension™ navigation system by physicians who are trained in endoscopic techniques for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

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."

Section 7: 510(k) Summary

The 510(k) Summary is included on the following page.

510(k) Summary
Covidien llc
Traditional 510(k)
Arcpoint™ pulmonary needle

1. Submitter

510(k) Submitter:
Covidien llc
161 Cheshire Lane, Suite 100
Plymouth, MN 55441 U.S.A.

Contact Person:
LeeAnne Swiridow
Sr. Regulatory Affairs Specialist
Phone: 763-210-1012
Fax: 763-210-4098
Email: leeanne.swiridow@medtronic.com

Date Prepared: 15 December 2016

2. Device

Trade Name :	Arcpoint™ pulmonary needle
Common Name:	Pulmonary Needle
Model Number:	ILS-1800-PN and ILS-2100-PN
Classification Name:	Bronchoscope (flexible or rigid) and accessories 21 CFR Part 874.4680
Product code:	EOQ

3. Predicate Device

Primary Predicate Device

Device Name :	Wang Transbronchial Aspriation Needle
510(k):	K914181
Classification Name:	Bronchoscope (flexible or rigid) and accessories 21 CFR Part 874.4680
Product code:	EOQ
Manufacturer:	ConMed Corporation

Secondary Predicate Device

Device Name :	GenCut™ Core Biopsy Tool
510(k):	K142839
Classification Name:	Bronchoscope (flexible or rigid) and accessories 21 CFR Part 874.4680
Product code:	EOQ
Manufacturer:	Covidien llc

4. Device Description

The Arcpoint™ pulmonary needle is an endobronchial biopsy needle that consists of a pulmonary needle and a stylet. The pulmonary needle is intended to retrieve tissue specimens from lungs during an endobronchial lung biopsy procedure. The product is used either through a flexible endoscope or in conjunction with the superDimension™ navigation system's extended working channel.

The pulmonary needle is comprised of an outer polymeric shaft with stainless steel braid reinforcement and an inner polymeric shaft with a stainless steel needle attached. The needle and device shaft are visible under fluoroscopy. The proximal end consists of handle connected to the outer shaft and a needle plunger with luer-lock fitting connected to the inner shaft. The pulmonary needle features a positive stop retraction/extension design which is controlled by sliding of the inner shaft via the needle plunger. When retracted, the needle stays within the outer shaft. The needle protrudes 8.0 mm from the outer shaft when fully extended. This design provides protection during passage in a working channel and allows accurate and quick release when the needle is at the targeted site. The luer-lock fitting allows connection to a standard luer-lock syringe for applying suction to the inner shaft to aspirate cell specimens.

A stylet comes pre-inserted in the pulmonary needle which provides additional rigidity to the needle shaft and may help prevent unwanted tissue capture during passage to the targeted site. Use of the stylet is optional at physicians' discretion. The product is packaged in a Tyvek pouch and is sterilized with ethylene oxide. The product package contains the pulmonary needle and stylet.

5. Indications for Use

The Arcpoint™ pulmonary needle is utilized through a flexible endoscope or with the superDimension™ navigation system by physicians who are trained in endoscopic techniques for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

6. Summary of Characteristics Compared to Predicate Devices

The Arcpoint pulmonary needle is substantially equivalent to the Wang Transbronchial Aspriation Needle cleared under K914181 and the GenCut core biopsy tool cleared under K142839. The Arcpoint pulmonary needle has the same technological characteristics as the predicates, that is, they are operate in the same manner to obtain a tissue biopsy in patient's lungs through a flexible endoscope or other working channel. Once they reach the target biopsy site, suction is applied through a syringe and a sample is taken from the desired site. Once the sample is obtained, the devices are withdrawn from the body and a sample can be expelled from the device.

Overall, the subject and primary predicate devices are all based on the following same technological elements:

- Device is introduced endoscopically and used to reach the target site,
- Device is inserted through a flexible endoscope or other working channel,
- Device features a sharpened, beveled, stainless steel needle, and is available in similar needle gauges,
- Device features a positive stop retraction/extension design which is controlled by sliding of the inner shaft via a plunger
- Use of a distal needle to collect tissues and a proximal hub to connect a luer-lock syringe in order to aspirate samples into the shaft,
- Device is intended for short-term introduction and transient use through a naturally occurring orifice.

The following primary technological differences exist between the subject and predicate devices:

- The pulmonary needle has shorter needle protrusion (8 mm) than the primary predicate device Wang Transbronchial Aspriation Needle (15 mm). The amount of needle protrusion does not impact needle performance because the tip geometry for the two products is essentially the same and it is the needle bevel that is critical for tissue collection.
- The pulmonary needle has a stylet that provides additional rigidity to the needle shaft during passage to the target site. The use of the style is optional.
- The pulmonary needle features a similar polymeric shaft with steel braid reinforcement as the secondary predicate device GenCut core biopsy tool. The primary predicate device features a PTFE sheath over a stainless steel shaft.

See table below for a detailed summary of the characteristics compared to the predicate devices.

Characteristic	**Wang Transbronchial Aspiration Needle (Predicate Device)** K914181	**GenCut™ core biopsy system (Secondary Predicate Device)** K142839	**Arcpoint™ pulmonary needle (Subject Device)**
Device Classification	Class II	Class II	Same
FDA Product Code	EOQ	EOQ	Same
Technological Characteristics			
Anatomical Site	Lung	Lung	Same
Introduction to Target Tissue	Endobronchial - Delivered to target tissue through a working channel	Endobronchial - Delivered to target tissue through a working channel	Same

Characteristic	Wang Transbronchial Aspiration Needle (Predicate Device) K914181	GenCut™ core biopsy system (Secondary Predicate Device) K142839	Arcpoint™ pulmonary needle (Subject Device)
Specimen Sampling Mechanism	Repeated axial motion with applied suction through a working channel	Repeated axial motion with applied suction through a working channel	Same
Cell Collection	Aspiration with a syringe	Aspiration with a syringe	Same
Working Outer Diameter	1.9 mm	1.8 mm	1.95 mm (.077")
Working Length	140 cm	106 cm - 115 cm	137 cm
Shaft Marks	No	Present	Present
Needle Tip	Sharpened	Blunted	Same
Needle Protrusion Length	15 mm	4.8 mm (Length)	8.0 mm
Retractable Distal End	Yes	No	Same
Radiopaque Distal End	Yes	Yes	Same
Material			
Working Outer Material	PTFE	Polymer: Copolyester Elastomer Braid: 304 Stainless Steel	Polymer: Copolyester Elastomer Braid: 304 Stainless Steel
Needle Material	Stainless Steel	Stainless Steel	Same

The bench and in-vivo animal study conducted demonstrate that the minor technological differences do not raise any different questions of safety and effectiveness and the subject device is as safe and as effective as the predicate devices. In conclusion, the Arcpoint pulmary needle is substantially equivalent to the predicate devices.

7. Performance Data

Non-clinical performance testing has been performed on the Arcpoint pulmonary needle and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- AAMI TIR 28:2009 *Product adoption and process equivalence for ethylene oxide sterilization*

- ISO 11135:2014 *Sterilization of Health Care Products – Ethylene Oxide: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*
- ISO 11138-2:2006 *Sterilization of Health Care Products – Biological Indicators – Part 2: Biological indicators for ethylene oxide sterilization processes*
- ISO 11607-1:2006 *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems*
- ISO 11607-2:2006 *Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes*
- ISO 11737-1:2006/(R)2011 *Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of the Population of Microorganisms on Product*
- ISO 14161: 2009 *Sterilization of Health Care Products – Biological Indicators – Guidance for the selection, use and interpretation of results*
- ISO 10993-1:2009(Corr: 2010) *Biological evaluation of medical devices – Part 1: Evaluation and testing*
- ISO 10993-5:2009 *Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-7:2008(Corr:2009) *Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals*
- ISO 10993-10:2010 *Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity*
- FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* June 16, 2016

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Data:

Biocompatibility testing was successfully completed in accordance with the FDA's Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued June 16, 2016 and International Standard ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process* as recognized by FDA. The following tests were conducted:

- Cytotoxicity
- Sensitization
- Intracutaneous Study
- Acute Systemic Toxicity and,

- Material-Mediated Pyrogenicity

Design Verification and Validation Testing Data:

Design verification and validation testing were conducted and demonstrated that the Arcpoint pulmonary needle meets defined product specification and its intended use. The design verification and validation testing included:

- Tensile Testing
- Shelf Life Testing
- Simulated Use Testing
- Sterilization
- Packaging and Distribution Testing
- Dimensional Testing

Animal Study Data:

A preclinical study was conducted in a porcine model undergoing an endobronchial lung biopsy procedure. Three physicians including two pulmonologists and one thoracic surgeon conducted the study with both the subject device and predicate device. Acceptance criteria for this study stated that there be no statistical difference between the subject device and the comparative device in the incidence of severe pneumothorax at 24 hour time point, severe intraoperative bleeding, bleeding (hemorrhage) at the time of necropsy, and severe pathological findings (trauma/tissue injury). All acceptance criteria were met. The results from the testing demonstrate that the subject device does not raise any different questions of safety and effectiveness when compared to the predicate device and has comparable performance to the predicate device. Therefore, Covidien believes that the Arcpoint pulmonary needle has been shown to be substantially equivalent to the predicate devices identified in this submission.

8. Substantial Equivalence Discussion

The proposed Arcpoint pulmonary needle is a sterile, single-use, biopsy needle designed for retrieving tissue specimens from lungs. The Arcpoint pulmonary needle has the same intended use, indications for use, anatomical site, principle of operation, and similar technological characteristics as the predicate devices identified in this submission.

Furthermore, the design verification testing and design validation testing performed demonstrate the subject device meets defined product specification and intended use. In addition, the bench and GLP animal comparison testing with the primary predicate device demonstrate that the subject device has comparable performance to the predicate device and minor technological characteristics differences do not raise any different questions of safety and effectiveness.

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate devices, Covidien believes that the Arcpoint™ pulmonary needle has been shown to be substantially equivalent to the predicate devices identified in this submission.