DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

June 17, 2015

Covidien llc
Deborah Fleetham
Regulatory Affairs Manager
161 Cheshire Lane, Suite 100
Plymouth, MN 55441

Re: K142934
Trade/Device Name: CrossCountry™ Transbronchial Access Tool
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOQ
Dated: May 15, 2015
Received: May 18, 2015

Dear Ms. Fleetham:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
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Enclosure

Indications for Use

510(k) Number (if known): K142934

Device Name: The CrossCountry™ Transbronchial Access Tool

Indications for Use:

The CrossCountry™ Transbronchial Access Tool is to be utilized through a flexible endoscope with an extended working channel by physicians who are trained in endoscopic techniques to puncture the tracheobronchial wall and facilitate access of additional endobronchial tools for patients with endobronchial lesions, peripheral lung nodules, or lung masses.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 7 510(k) Summary

The 510(k) Summary for the CrossCountry™ transbronchial access tool is included on the following page.

510(k) Summary
Covidien llc.
Traditional 510(k)
CrossCountry™ Transbronchial Access Tool

I. Submitter

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Date Prepared : June 12, 2015:

II. DEVICE

Trade Name :	CrossCountry™ Transbronchial Access Tool
Common Name:	Endoscopic Tool
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	21 CFR 874.4680
Product code:	EOQ

III. PREDICATE DEVICE(S)

Primary Predicate:	LungPoint Tools (LungPoint Sheath and LungPoint Dilation Balloon) K131234
Common Name:	Sheath and Dilation Balloon
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	21 CFR 874.4680
Product code:	EOQ

Secondary Predicate:	Wang Transbronchial Aspiration Needle – K914181
Common Name:	Transbronchial Needle
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	21 CFR 874.4680
Product code:	EOQ

Primary Predicate:	LungPoint Tools (LungPoint Sheath and LungPoint Dilation Balloon) - K131234

Secondary Predicate: Wang Transbronchial Aspiration Needle – K914181

No additional reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The CrossCountry™ transbronchial access tool (CrossCountry Tool) is a flexible endobronchial tool made up of two components: a wire and a catheter. The wire is used inside of the catheter. The product is used through a flexible endoscope with an extended working channel. The CrossCountry tool is designed to puncture a hole in the tracheobronchial wall then, using the catheter to dilate the channel, allows for subsequent endoscopic tool placement. This allows for access to lesions without a bronchus sign (outside the airways).

The product is packaged in a Tyvek™[1] pouch and sterilized with ethylene oxide.

V. INDICATION FOR USE

The CrossCountry™ transbronchial access tool is to be utilized through a flexible endoscope with an extended working channel by physicians who are trained in endoscopic techniques to puncture the tracheobronchial wall and facilitate access of additional endobronchial tools for patients with endobronchial lesions, peripheral lung nodules, or lung masses.

VI. SUMMARY OF CHARACTERISTICS COMPARED TO PREDICATE DEVICE

Transbronchial endoscopic techniques are the foundation for the CrossCountry tool and both the primary and secondary predicate. All of these tools are intended to access lung lesions. At a high level, the subject and predicate devices are based on the following technological elements:

- All are introduced endoscopically and used to reach the target lung tissue
- Each device is inserted through a channel which can be a bronchoscope or other working channel.
- All are transient devices intended for short-term introduction through a naturally occurring orifice.
- The CrossCountry tool and the Wang Transbronchial Aspiration Needle have sharp distal ends to puncture the tracheobronchial wall.

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

[1] Trademark of its respective owner

Characteristic	CrossCountry Tool	Broncus Medical Inc. Lungpoint Tools (Primary Predicate) K131234	Wang Transbronchial Aspiration Needle (Secondary Predicate) K914181
Device Classification	Class II	Class II	Class II
FDA Product Code	EOQ	EOQ	EOQ
Technological Characteristics			
Components	Wire and Catheter	LungPoint Sheath and LungPoint Balloon	Transbronchial Aspiration Needle
Single Use	Yes	Yes	Yes
Anatomical Location	Lung	Lung	Lung
Introduction into the body	Endobronchial	Endobronchial	Endobronchial
Sharp Distal Tip	Yes - Wire	Not known	Yes - Needle
Radiopaque distal end	Yes	Yes	Yes
Dilation Ability	Yes	Yes	No
Dilation Mechanism	Mechanical	Pneumatic	None
Working Outer Diameter	Catheter OD: 2.01mm Wire OD: 0.66mm	Sheath - 2.65 mm Balloon: 1 mm (uninflated) 4 mm (inflated)	Tip OD: 1.9 mm
Working Length	Catheter: 109.9 cm Wire: 116.1 cm	Sheath: 90 cm Balloon: 97.5 cm	130 cm
Tip Diameter	Catheter: Tapers down to slightly larger than the wire - Wire: 0.41mm	Not applicable	22 gauge needle (0.028 in / 0-71mm)
Material			
Working Outer Material	Polymer – Copolyester Elastomer Braid – 304 Stainless Steel	Not Known	PTFE
Wire Tip Wire	Titanium Nitinol	Not Known	Stainless Steel

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

- The CrossCountry tool dilates using mechanical pressure while the LungPoint Tools dilate using pneumatic pressure.

- The CrossCountry tool incorporates a sharp wire tip to puncture the tracheobronchial wall while the LungPoint Tool must rely on a separate device to puncture the wall.
- The CrossCountry tool provides access for other endoscopic tools to sample tissue while the Wang transbronchial aspiration needle is able to sample tissue directly.

VII. PERFORMANCE DATA

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

Biocompatibility Data:
Biocompatibility testing was completed in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993 "Biological Evaluation fo Medical Devices Part 1: Evaluation and Testing" May 1, 1995 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 Reactivity

Design Verification and Validation Testing Data:

- Tensile Testing
- Shelf Life Testing
- Simulated Use Testing
- Distribution Testing
- Compatibility Testing
- Dimensional Testing

Animal Study Data:
A preclinical study was conducted using the CrossCountry access tool on one side of the lung and a control device on the opposite side of the lung. All of the acceptance criteria were met. This study showed the CrossCountry access tool design meets its intended use.

VIII. SUBSTANTIAL EQUIVALENCE CONCLUSION

Covidien llc has demonstrated that the proposed CrossCountry access tool is substantially equivalent to the LungPoint Tools and the Wang Transbronchial Aspiration Needle which are legally marketed for the same intended use. The non-clinical data and the in-vivo animal study provide adequate justification to demonstrate that the CrossCountry access tool should perform as intended in the specified use condition.