January 14, 2021

Broncus Medical, Inc
Robin Bush
VP, Regulatory Affairs and Quality Assurance
125 Nicholson Lane
San Jose, California 95134

Re: K200702
Trade/Device Name: EasyPath RF Introducer Sheath
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, EOQ
Dated: December 21, 2020
Received: December 23, 2020

Dear Robin Bush:

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,

*for* Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200702

Device Name

EasyPath RF Introducer Sheath

Indications for Use *(Describe)*

The EasyPath RF Introducer Sheath is a single-use device intended to be used with flexible bronchoscopes as a working channel through which endoscopic tools may be introduced to target tissue. It is indicated for electrosurgical procedures involving cutting and coagulation of soft tissue in the upper airways and 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.**

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.***

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**510(k) SUMMARY**

## I. DATE PREPARED

December 11, 2020

## II. 510(k) SUBMITTER

Broncus Medical, Inc.
125 Nicholson Lane
San Jose, CA 95134

Contact Person: Robin Bush, VP Regulatory Affairs and Quality Assurance
650-428-1600 x 348

## III. DEVICE

| | |
|---|---|
| Trade Name of Device: | EasyPath RF Introducer Sheath (Model 10011) |
| Device Class: | Class II |
| Classification Name: | Bronchoscope (Flexible and Rigid) and Accessories / Electrosurgical cutting and coagulation device and accessories |
| Regulation Number: | 21 CFR 878.4400 |
| Product Code: | GEI (Primary)<br>EOQ (Secondary) |

## IV. PREDICATE DEVICES

**Multiple Predicate Device Information:**

| **Primary Predicate Device** | **Manufacturer** | **510(k)#** | **Clearance Date** |
|---|---|---|---|
| Empower RF Catheter | Broncus Medical, Inc. | K183240 | February 22, 2019 |
| **Secondary Predicate Device** | **Manufacturer** | **510(k)#** | **Clearance Date** |
| Archimedes Sheath (current commercial name)<br><br>[Cleared as LungPoint Tools: LungPoint Sheath and LungPoint Dilation Balloon] | Broncus Medical, Inc. | K131234 | October 15, 2013 |

## V. DEVICE DESCRIPTION

The EasyPath RF Introducer Sheath is a sterile, single-use, monopolar endoscopic device intended to be inserted through the working channel of a flexible bronchoscope, with an inner diameter (ID) of 2.8 mm or greater, which provides an extended working channel through which endoscopic tools, such as needles, biopsy forceps, or other endoscopic devices may be

introduced to target sites. Similar to Empower RF Catheter, the EasyPath incorporates a distal electrode for delivering RF energy for cutting and coagulation of soft tissue in the upper airways and tracheobronchial tree. The monopolar electrode at the distal tip facilitates cutting the target tissue using controlled monopolar radiofrequency (RF) energy.

The EasyPath has a flexible shaft with a 2.65 mm OD with braid reinforced tubing and a stylet, to resist kinking during device advancement and articulation. The stylet is used to provide an atraumatic tip and to provide rigidity (i.e., pushability). Removal of the stylet allows for standard 2.0 mm working channel bronchoscopic accessories to be inserted through the lumen of the sheath. The electrode tip of the sheath is visible, as well as the marker bands to provide the user with an indication of movement relative to the bronchoscope. Radiopaque markers are at the distal end of the sheath to aid visualization of the sheath under fluoroscopy, if utilized.

## VI. INDICATIONS FOR USE

The EasyPath RF Introducer Sheath is a single-use device intended to be used with flexible bronchoscopes as a working channel through which endoscopic tools may be introduced to target tissue. It is indicated for electrosurgical procedures involving cutting and coagulation of soft tissue in the upper airways and tracheobronchial tree.

## VII. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

The EasyPath RF Introducer Sheath is substantially equivalent to legally marketed predicate devices. The EasyPath RF Introducer Sheath is substantially equivalent in intended use, indications for use, technological characteristics and principles of operation to the Broncus Empower RF Catheter and the Broncus Archimedes Sheath and, cleared by FDA in K183240 and K131234, respectively.

The EasyPath Introducer Sheath is substantially equivalent to multiple predicate devices. The EasyPath RF Introducer Sheath has the same intended use and combines the indications for use, technological features and functions of the Broncus Empower RF Catheter (K183240), as well as the Broncus Archimedes Sheath (K131234; cleared as the LungPoint Tools: LungPoint Sheath, LungPoint Dilation Balloon). These devices are all intended for use during interventional bronchoscopy procedures involving soft tissue in the upper airways and tracheobronchial tree, as determined by the physician performing the bronchoscopy. Similar to the Empower RF Catheter, the EasyPath combines the features of an RF electrode to enable physicians to cut target tissue via RF energy, as well as the features and functions of an introducer sheath with working channel, similar to the cleared Archimedes Sheath. Similar to the predicate devices, the EasyPath is designed to be used with flexible bronchoscopes of 2.8 mm or greater in the upper airways and tracheobronchial tree, allowing introduction of endoscopic tools for use at target sites.

Key technological characteristics of the EasyPath Introducer RF Sheath are compared to the predicate devices in the following table. The table illustrates equivalence of the subject EasyPath RF Introducer Sheath to the primary and secondary predicate devices, Empower (K183240) and Archimedes Sheath (K131234). A discussion regarding any technological differences in the subject device (EasyPath RF Introducer Sheath), when compared to the predicate devices, is provided below the table.

| Substantial Equivalence Comparison of Key Technological Characteristics | | | | |
|---|---|---|---|---|
| **Feature** | **EasyPath RF Introducer Sheath Subject Device** | **Primary Predicate Empower RF Catheter (Empower) K183240** | **Secondary Predicate Archimedes Sheath (aka LungPoint Tools/Sheath) K131234** | **Differences (Justification for Equivalency)** |
| Intended Use | Intended for use in interventional bronchoscopy procedures involving soft tissue of the upper airways and tracheobronchial tree.<br><br>Introduced through a flexible bronchoscope, facilitates site access, and use of other endoscopic surgical devices. | Intended for use in interventional bronchoscopy procedures involving removal/cutting (incision, vaporization, ablation, coagulation and hemostasis) of soft tissues of the upper airways and tracheobronchial tree.<br><br>Introduced through a flexible bronchoscope. | Intended for use in interventional bronchoscopy procedures involving soft tissue of the bronchial tree.<br><br>Introduced through a flexible bronchoscope, facilitates site access and use of other endoscopic surgical devices. | **Same intended use therefore, equivalent** |
| Indications for Use | The EasyPath RF Introducer Sheath is a single-use device intended to be used with flexible bronchoscopes as a working channel through which endoscopic tools may be introduced to target tissue.<br><br>It is indicated for electrosurgical procedures involving cutting and coagulation of soft tissue in the upper airways and tracheobronchial tree. | The Empower RF Catheter is a single-use, electrosurgical device designed to be used with flexible bronchoscopes.<br><br>It is indicated for electrosurgical procedures involving soft tissue obstructions in the upper airways and tracheobronchial tree. | The LungPoint Tools are endoscopic tools intended to be used with LungPoint Software guided bronchoscopes.<br><br>The LungPoint Sheath is intended to be used as a working channel through which endoscopic tools may be introduced to targeted tissue or directly through the working channel of the bronchoscope. | The EasyPath and Empower are indicated for electrosurgical procedures involving soft tissue in the upper airways and tracheobronchial tree.<br><br>The EasyPath and Archimedes Sheath, are working channels through which endoscopic tools may be introduced to targeted tissue.<br><br>**Same combined indications for use in the same anatomy; therefore, equivalent.** |

| Substantial Equivalence Comparison of Key Technological Characteristics | | | | |
|---|---|---|---|---|
| **Feature** | **EasyPath RF Introducer Sheath Subject Device** | **Primary Predicate Empower RF Catheter (Empower) K183240** | **Secondary Predicate Archimedes Sheath (aka LungPoint Tools/Sheath) K131234** | **Differences (Justification for Equivalency)** |
| User | Qualified physicians: Interventional pulmonologists, thoracic surgeons, and pulmonary technologists | Qualified physicians: Interventional pulmonologists, thoracic surgeons, and pulmonary technologists | Qualified physicians: Interventional pulmonologists, thoracic surgeons, and pulmonary technologists | **Same, therefore, equivalent.** |
| Method of Introduction | Flexible bronchoscope with minimum working channel of 2.8mm | Flexible bronchoscope or minimum working channel of 2.0mm | Flexible bronchoscope with a minimum working channel of 2.8mm | Introduced through flexible bronchoscopes; the OD diameter of EasyPath is the same as the Archimedes Sheath to allow the smaller OD treatment devices (such as the Empower) to pass through the Sheaths.<br>**Similar, therefore, equivalent.** |
| Delivery Approach | Visual (via bronchoscope); Optional – virtual bronchoscopic navigation system | Visual (via bronchoscope); Optional – virtual bronchoscopic navigation system | Visual (via bronchoscope); Optional – virtual bronchoscopic navigation system | **Same, therefore, equivalent.** |
| Target Tissue | Soft tissue in the upper airways and tracheobronchial tree | Soft tissue obstructions in the upper airways and tracheobronchial tree | Soft tissue in the upper airways and tracheobronchial tree | **Same, therefore, equivalent.** |
| Tip Type | Blunt atraumatic tip | Ball point (blunt) | Blunt atraumatic tip | **Similar atraumatic tip shapes; therefore, equivalent.** |
| Catheter OD | 2.65 mm | 1.8 mm | 2.65 mm | Similar to Empower and Identical to Archimedes; fit through a 2.8 mm flexible bronchoscope.<br>**Similar OD; therefore, equivalent.** |

| Substantial Equivalence Comparison of Key Technological Characteristics | | | | |
|---|---|---|---|---|
| **Feature** | **EasyPath RF Introducer Sheath Subject Device** | **Primary Predicate Empower RF Catheter (Empower) K183240** | **Secondary Predicate Archimedes Sheath (aka LungPoint Tools/Sheath) K131234** | **Differences (Justification for Equivalency)** |
| Working Length | 900 mm | 1445 mm | 900 mm | EasyPath and Archimedes have the same working length.<br>The longer working length of the Empower allows it to extend through the end of the working sheaths.<br>**Same as Archimedes Sheath; less than Empower; therefore, equivalent.** |
| Radiopaque Markers | Yes | Yes | Yes | **Same** |
| Energy Used | Monopolar RF energy | Monopolar RF energy | Not applicable | **Same** |
| Energy Source | Commercially available, compatible electrosurgical units | Commercially available, compatible electrosurgical units | Not applicable | **Same** |
| Generator Power Setting | 10-75W | 7- 50W | Not applicable | Power settings typically used are less than maximum.<br>Performance testing was performed at maximum settings.<br>**Similar; therefore, equivalent.** |
| Applied RF Time and Generator Effect Setting | Activate until desired tissue effect is achieved, generally 1-3 seconds | Activate until desired tissue effect is achieved, generally <30 minutes | Not applicable | Adjustable power, effect setting, and time.<br>**Similar to Empower; therefore, equivalent.** |
| Electrode Material | Platinum Iridium | Stainless Steel | Not applicable | **Similar; therefore, equivalent** |
| Single Use | Yes | Yes | Yes | **Same** |

| Substantial Equivalence Comparison of Key Technological Characteristics | | | | |
|---|---|---|---|---|
| **Feature** | **EasyPath RF Introducer Sheath Subject Device** | **Primary Predicate Empower RF Catheter (Empower) K183240** | **Secondary Predicate Archimedes Sheath (aka LungPoint Tools/Sheath) K131234** | **Differences (Justification for Equivalency)** |
| Packaging Materials | Pouch: Tyvek / polyethylene | Pouch: Tyvek / polyethylene | Pouch: Tyvek / polyethylene | **Same** |
| Sterilization Method | Ethylene Oxide | E-beam | E-beam | Standard sterilization methods<br><br>**Similar; therefore, equivalent** |
| Sterility Assurance Level | $10^{-6}$ | $10^{-6}$ | $10^{-6}$ | **Same** |

As presented above, the larger OD (outer diameter) of 2.65 mm and a shorter minimum working channel (900 mm) of the EasyPath allows bronchoscopic devices of smaller OD and longer length, such as the Empower Catheter, to be introduced through the EasyPath Sheath and extend through the end of the device to reach distal regions of the tracheobronchial tree. The devices are designed for to be used with a wide range of bronchoscopes with a minimum diameter of 2.8 mm. EasyPath and Archimedes have the same working length.

Recommended power settings for the generator vary depending on use. The RF application time for EasyPath is seconds, compared to minutes for Empower RF Catheter. Verification and performance data confirm the time and settings for the devices; these differences do not affect product performance, and do not raise new issues of safety or effectiveness. The instructions for use for EasyPath and Empower include statements to use the lowest power and effect setting to achieve the desired tissue effect.

Sterilization methods used are standard methods of sterilization for medical devices. The same test methods, shelf life, accelerated aging and performance testing were used to confirm the EasyPath RF Introducer Sheath meets specifications at the end of shelf-life. The different sterilization method has no impact on biocompatibility, sterility assurance level or product performance.

The minor differences in dimensional characteristics, such as length and diameter, between the subject and predicate device, does not affect the device's intended use or principles of operation. As such, these differences do not raise additional questions on safety and effectiveness; therefore, the EasyPath RF Introducer Sheath is substantially equivalent to the predicate devices.

## VIII. PERFORMANCE DATA

Design verification testing was performed for the EasyPath RF Introducer Sheath to demonstrate that the device meets product specifications and is safe and effective for its intended clinical use. As applicable, design verification testing was performed according to recognized standards. The following testing was provided for the subject 510(k) and supports the substantial equivalence of the EasyPath RF Introducer Sheath to the predicate devices:

- Biocompatibility Testing; in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
  - Cytotoxicity
  - Maximization Sensitization
  - Intracutaneous Irritation
  - Acute Systemic Toxicity
  - USP Pyrogen
  - Phthalates
- Sterilization Validation; in accordance with ISO 11135:2014, *Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices*
- Packaging Verification and Shelf-Life Testing; in accordance with ISO 11607-1 and ASTM-1980
- Electrical Safety and EMC Safety Testing, in accordance with:
  - IEC 60601-1:2005 and A1:2012, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
  - IEC 60601-1-2:2014, *General requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - rRequirements and tests*
  - IEC 60601-2-2:2017, *Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
  - BS EN 60601-2-18:2015, *Particular requirements for the basic safety and essential performance of endoscopic equipment*
- Bench Performance Testing:
  - Packaging Inspection
  - Dimensional Inspection
  - Electrical Inspection
  - Visible Market Band Inspection
  - Simulated Use testing
  - Tensile Testing
  - Ex-vivo RF Application Testing
  - Corrosion Resistance
  - Radiopacity Verification
  - Scope Visualization
  - Leak Resistance
- In vivo Porcine Lung Thermal Testing

## IX. CONCLUSIONS

The EasyPath RF Introducer Sheath share the same intended use, and combined indications for use and technological features as the cleared Empower RF Catheter (K183240) and Archimedes Sheath (K131234). It is substantially equivalent in intended use / indications for use, as well as technological characteristics and principles of operation to the predicate devices. The minor differences in dimensions or characteristics between the subject and the predicate devices do not raise new concerns of safety and effectiveness.

Design verification testing included biocompatibility, sterilization validation, packaging and shelf life studies, electrical, and thermal safety, as well as performance and in vivo testing. The results of verification and validation demonstrate reasonable assurance of safety and effectiveness.

The data and information provided within this premarket notification demonstrates that EasyPath RF Introducer Sheath is safe and effective for its intended clinical use and does not introduce or raise new questions of safety and effectiveness, The EasyPath RF Introducer Sheath is as safe, as effective and performs as well as the predicate devices, is substantially equivalent to the predicate devices, thereby supporting a determination of substantial equivalence.