February 22, 2019

Broncus Medical, Inc
Aradhana Dhanabal
Regulatory Affairs Manager
125 Nicholson Lane
San Jose, California 95134

Re: K183240

Trade/Device Name: Empower RF Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 19, 2019
Received: February 21, 2019

Dear Aradhana Dhanabal:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
**Indications for Use**

510(k) Number *(if known)*
K183240

Device Name
Empower RF Catheter

Indications for Use *(Describe)*
The Empower RF Catheter is a single-use, electrosurgical device designed to be used with flexible bronchoscopes. It is indicated for electrosurgical procedures involving soft tissue obstructions in the upper airways and tracheobronchial tree.

Type of Use *(Select one or both, as applicable)*

- [x] 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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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.*
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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

PRIMARY CONTACT  Aradhana Dhanabalan
Regulatory Affairs Manager
Broncus Medical, Inc.
Phone: 650-428-1600 Ext.311
Email: adhanabalan@broncus.com

SECONDARY CONTACT  Liz Raphael
Senior Regulatory Affairs Manager
Broncus Medical, Inc.
Phone: 408-728-1037
Email: lraphael@broncus.com

DATE PREPARED  February 15, 2019

TRADE NAME  Empower RF Catheter

COMMON NAME  Radiofrequency (RF) Catheter

CLASSIFICATION NAME  Electrosurgical cutting and coagulation devices and accessories

DEVICE CLASSIFICATION  Class II, 21 CFR §878.4400

PRODUCT CODE  GEI

PREDICATE DEVICES  EC 2.7 Endoscopic Cutter (K120909)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION
The Empower RF Catheter is a sterile, single-use monopolar endoscopic device intended to be inserted through a flexible bronchoscope or a working channel of a flexible bronchoscope with an inner diameter of 2.0 mm.
It has a stainless-steel electrode at the distal end, a flexible catheter shaft comprised of a nitinol wire covered by insulation tubing to prevent kinking and facilitate pushability during bronchoscopic procedures and a standard male banana plug at the proximal end.

The banana plug connects to a monopolar connecting cable of a compatible electrosurgical unit. Empower is activated by a footswitch accessory supplied with the electrosurgical unit. Empower is provided in a monopolar configuration and thus, must be used in conjunction with a commercially available compatible patient return electrode to complete the return path for the RF electrical current.

**INTENDED USE**
The Empower RF Catheter is intended to be inserted through the working channel of a flexible bronchoscope and utilized in electrosurgical procedures involving removal/cutting of soft tissues (incision, vaporization, ablation, coagulation and hemostasis).

**INDICATION FOR USE**
The Empower RF Catheter is a single-use, electrosurgical device designed to be used with flexible bronchoscopes. It is indicated for electrosurgical procedures involving soft tissue obstructions in the upper airways and tracheobronchial tree.

**SUBSTANTIAL EQUIVALENCE TO**
Empower is substantially equivalent to the legally marketed predicate device, the EC 2.7 Endoscopic Cutter (K120909). The subject device has the same intended use, indications for use and substantially the same technological characteristics.

The comparison table below, Table 1, presents side by side comparisons between both the devices. The table illustrates equivalence of the subject Empower RF Catheter to the predicate EC 2.7 Endoscopic Cutter.

<table>
<thead>
<tr>
<th>Device Name→ Device Characteristics ↓</th>
<th>Empower RF Catheter (Subject Device)</th>
<th>EC 2.7 Endoscopic Cutter (K120909) (Predicate Device)</th>
<th>Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Classification</td>
<td>Class II</td>
<td>Class II</td>
<td>Same</td>
</tr>
<tr>
<td>Code of Federal Regulations</td>
<td>878.4400</td>
<td>878.4400</td>
<td>Same</td>
</tr>
<tr>
<td>Prescription or OTC</td>
<td>Prescription</td>
<td>Prescription</td>
<td>Same</td>
</tr>
<tr>
<td>Device Type</td>
<td>Sterile, Single-Use</td>
<td>Sterile, Single-Use</td>
<td>Same</td>
</tr>
<tr>
<td>Device Characteristics ↓</td>
<td><strong>Empower RF Catheter (Subject Device)</strong></td>
<td><strong>EC 2.7 Endoscopic Cutter (K120909) (Predicate Device)</strong></td>
<td>Differences</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------------</td>
<td>-------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>The Empower RF Catheter is intended to be inserted through the working channel of a flexible bronchoscope and utilized in electrosurgical procedures involving removal/cutting of soft tissues (incision, vaporization, ablation, coagulation and hemostasis).</td>
<td>The EC 2.7 Endoscopic Cutter is intended to be inserted through the working channel of a flexible bronchoscope having an instrument channel diameter of 2.8 mm minimum, a working length of 600 mm, activated by a foot-switch connected to a qualified electrosurgical generator, and utilized in electrosurgical procedures involving removal/cutting of soft tissues (excision, incision, vaporization, ablation) while also providing electrosurgical coagulation and hemostasis.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Indications for use</strong></td>
<td>The Empower RF Catheter is a single-use, electrosurgical device designed to be used with flexible bronchoscopes. It is indicated for electrosurgical procedures involving soft tissue obstructions in the upper airways and tracheobronchial tree.</td>
<td>The EC 2.7 Endoscopic Cutter is a single use electrosurgical instrument designed to be used with flexible bronchoscopes and qualified electrosurgical units. It is indicated for cutting of soft tissue obstructions in upper airways and tracheobronchial tree, and provision of electrosurgical hemostasis during such procedures.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Target Tissue</strong></td>
<td>Soft Tissue obstructions in the upper airways and tracheobronchial tree.</td>
<td>Soft Tissue obstructions in the upper airways and tracheobronchial tree.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Access Method</strong></td>
<td>Flexible Bronchoscope with minimum working channel of 2.0 mm</td>
<td>Flexible Bronchoscope with minimum working channel of 2.8 mm</td>
<td>Different, discussion below</td>
</tr>
<tr>
<td><strong>Energy Used</strong></td>
<td>Monopolar RF</td>
<td>Monopolar RF</td>
<td>Same</td>
</tr>
<tr>
<td>Device Name</td>
<td>Empower RF Catheter (Subject Device)</td>
<td>EC 2.7 Endoscopic Cutter (K120909) (Predicate Device)</td>
<td>Differences</td>
</tr>
<tr>
<td>-------------</td>
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<td>---------------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Device Characteristics ↓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy Source</td>
<td>Compatible Electrosurgical Generators</td>
<td>Compatible Electrosurgical Generators</td>
<td>Same</td>
</tr>
<tr>
<td>Operating Principle</td>
<td>Uses heat delivered via a distal tip electrode to facilitate treatment through thermal necrosis</td>
<td>Uses heat delivered via a distal tip electrode to facilitate treatment through thermal necrosis</td>
<td>Same</td>
</tr>
<tr>
<td>Operating Mode</td>
<td>Monopolar configuration requires patient return electrode</td>
<td>Monopolar configuration requires patient return electrode</td>
<td>Same</td>
</tr>
<tr>
<td>Device Components</td>
<td>Active electrode, catheter shaft, electrical connector</td>
<td>Active electrode, catheter shaft, electrical connector</td>
<td>Same</td>
</tr>
<tr>
<td>Active Electrode</td>
<td>Stainless steel tip</td>
<td>Similar biocompatible electrode materials</td>
<td>Similar biocompatible materials; hence equivalent</td>
</tr>
<tr>
<td>Catheter Shaft</td>
<td>Flexible shaft, polymeric materials</td>
<td>Flexible shaft, polymeric materials</td>
<td>Similar biocompatible materials; hence equivalent</td>
</tr>
<tr>
<td>Electrical Connector</td>
<td>Banana Plug</td>
<td>Electrical adaptor</td>
<td>Similar electrical port; hence equivalent</td>
</tr>
<tr>
<td>Catheter Outer Diameter (OD)</td>
<td>1.8 mm</td>
<td>2.68 mm</td>
<td>Different, discussion below</td>
</tr>
<tr>
<td>Working Length</td>
<td>1445 mm (minimum)</td>
<td>750 mm</td>
<td>Different, discussion below</td>
</tr>
<tr>
<td>Sterilization</td>
<td>E-Beam (SAL=10⁻⁶)</td>
<td>Ethylene Oxide (SAL=10⁻⁶)</td>
<td>Similar Sterility Assurance Level; hence equivalent</td>
</tr>
</tbody>
</table>

A smaller OD (outer diameter) and a longer minimum working channel allows Empower to be used with a wide range of bronchoscopes and the longer working length allows greater flexibility and convenience during equipment setup and scope access. Since the difference between the subject and predicate device include minor differences in dimensional characteristics such as lengths and diameters, it does not alter the device’s intended use or principle of operation. As such, these differences do not raise additional questions on safety and effectiveness, and therefore Empower RF Catheter is considered **substantially equivalent** to the predicate.
PERFORMANCE DATA

Performance testing has been completed to demonstrate substantial equivalence of the subject device to the predicate device. Empower was subjected to the following verification and validation tests, as applicable:

Biocompatibility

Biocompatibility verification was performed for patient contacting components of Empower in accordance with:

- ISO 10993-10:2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization

Sterilization and Shelf Life Testing

Empower was validated to achieve sterility assurance level of $10^{-6}$ and adopted into a validated E-beam sterilization cycle. Packaging validation was performed to ensure that the device maintains package integrity, sterility and labeling requirements.

Sterilization validation was performed in accordance with:

- AAMI TIR 33:2005 Sterilization of Health Care Products-Radiation- Substantiation of a selected sterilization dose – Method VDmax
- ISO 11137-1:2006/Amd 2013 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Electrical Safety Testing

Electrical safety testing was performed for the applicable components of Empower. The results demonstrated compliance to all applicable requirements of the below standards:

- IEC 60601-1:2006 General requirements for basic safety and essential performance
- IEC 60601-2-2:2009 Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 60601-2-18:2015 Particular requirements for the basic safety and essential performance of endoscopic equipment
Performance Bench Testing

The following performance bench tests were performed:

- Tensile Testing
- Packaging Inspection
- Dimensional Inspection
- Electrical Inspection
- Simulated Use testing
- Corrosion Resistance
- Radiopacity verification
- Scope Visualization
- Ex-vivo ablation testing

Biocompatibility testing, sterilization and shelf life testing, electrical safety testing, and performance bench testing were performed on Empower. The results from this testing demonstrates that Empower meets the defined design requirements and supports its safety and effectiveness for its intended use and its substantial equivalence to the predicate device.

CONCLUSION

The Empower RF Catheter and the predicate device share the same intended use, indications for use, and performance characteristics. The minor differences in dimensional characteristics between the subject and the predicate device do not raise any new concerns of safety and effectiveness. Furthermore, the results of verification and validation demonstrate reasonable assurance of safety and effectiveness.

The data and information presented within this 510(k) premarket notification supports a determination of substantial equivalence to the predicate device, and market clearance of the Empower RF Catheter.