May 31, 2024

Broncus Medical, Inc
Antoinette M. Clay
Sr. Regulatory Affairs Specialist
125 Nicholson Lane
San Jose, California 95134

Re: K232601
Trade/Device Name: BroncTru Transbronchial Access Tool
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: May 31, 2024
Received: April 9, 2024

Dear Antoinette M. Clay:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K232601

Device Name
BroncTru Transbronchial Access Tool

Indications for Use *(Describe)*

The BroncTru Transbronchial Access Tool is indicated for use in conjunction with a flexible bronchoscope to puncture the lung, dilate, and establish a working channel, facilitating the guidance of other endoscopic tools to reach target lesions.

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.**

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## I. GENERAL INFORMATION

| | |
|---|---|
| **Manufacturer & 510(k) Submitter:** | Broncus Medical, Inc.<br>125 Nicholson Lane<br>San Jose, CA 95134 USA<br>Phone: (650) 428-1600<br>Fax: (650) 428-1542 |
| **Establishment Registration Number:** | 3007867778 |
| **Primary Contact:** | Antoinette M. Clay<br>Sr. Regulatory Affairs Specialist<br>(650) 428-1600<br>aclay@broncus.com |
| **Secondary Contact:** | Gloria Dy<br>Sr. Regulatory Affairs Specialist<br>(650) 428-1600 Extn. 311<br>gdy@broncus.com |
| **Date Prepared:** | May 31, 2024 |
| **Device Subject to this 510(k):** | BroncTru Transbronchial Access Tool |
| **Description** | The BroncTru Transbronchial Access Tool is a single-use sterile disposable catheter with a puncture needle, dilator and a sheath, which is suitable for use with standard flexible optical bronchoscopes with a working channel of ≥2.0 mm and ≥2.8 mm designed to establish a working channel in the lung to allow other endoscopic tools to reach the target lesion. |
| **Trade Name:** | BroncTru Transbronchial Access Tool |
| **Generic/Common Name:** | Endoscopic Tool |
| **Device Classification Name:** | Bronchoscope (flexible or rigid) and accessories |
| **Regulation Number:** | 21 CFR 874.4680 |
| **Product Code:** | EOQ |
| **Classification:** | Class II |

**II. PREDICATE DEVICE:**

| | |
|---|---|
| **(Trade Name)** | Covidien LLC CrossCountry™ Transbronchial Access Tool. |
| Predicate Device Common Name: | Endoscopic Tool |
| **Predicate 510(k) Number:** | K142934 |
| **Classification Name:** | Bronchoscope (flexible or rigid) and accessories |
| **Regulation Number:** | 21 CFR 874.4680 |
| **Product Code:** | EOQ |
| **Classification:** | Class II |

| | |
|---|---|
| **III. REFERENCE DEVICE:** | LungPoint™ Tool (LungPoint Sheath and LungPoint Dilation balloon) |
| **Device Common Name:** | Sheath and Dilation Balloon |
| **Referenced 510(k) Number:** | K131234 |
| **Classification Name:** | Bronchoscope (flexible or rigid) and accessories |
| **Regulation Number:** | 21 CFR 874.4680 |
| **Product Code:** | EOQ |
| **Class:** | Class II |

## 2. DEVICE DESCRIPTION

BroncTru Transbronchial Access Tool is a single-use sterile disposable catheter made up of four (4) components:

i) *Needle* – used for puncturing of the transbronchial wall.
ii) *Dilator* – the long-tapered tip dilator is used to dilate the opening in the transbronchial wall created by the needle. It also provides protection around the sharp needle tip during vascular access.
iii) *Sheath* - the sheath inserted into the dilated tracheobronchial wall, provides a port through which a variety of endoscopic tools can be inserted.
iv) *Handle* - The handle is operated by the operator to advance and to pull the dilator out leaving only the sheath to guide other devices to the target.

The BroncTru Transbronchial Access Tool is designed to puncture the tracheobronchial wall, the long-tapered tip of the dilator acts to stretch the opening in the tracheobronchial wall to allow for the insertion of the larger sheath. The dilator is then removed, leaving only the sheath inserted into the tracheobronchial wall, providing a channel which allows for subsequent endoscopic tool placement. This allows for access to lesions without a bronchus sign (outside the airways).

## 3. INDICATION FOR USE.

The *BroncTru Transbronchial Access Tool* is indicated for use in conjunction with a flexible bronchoscope to puncture the lung, dilate, and establish a working channel, facilitating the guidance of other endoscopic tools to reach target lesions.

The Target Population is patients aged 18 to <22 years (transitional pediatrics) and adults >22 years who need to establish a working channel in the lung to allow other endoscopic tools to reach the target lesion.

The Indication for Use and intended use are similar to that of the predicate device – The Covidien LLC's *CrossCountry™ Transbronchial Access Tool* cleared in 510(k) Number [K142934].

## 4. SUMMARY OF CHARACTERISTICS COMPARED TO PREDICATE DEVICE.

Transbronchial endoscopic techniques are the foundation for the *BroncTru Transbronchial Access Tool* and for both the predicate and reference devices. 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.
- Both the subject device *BroncTru Transbronchial Access Tool* and the predicate device - *CrossCountry™ Transbronchial Access Tool* have sharp distal ends to puncture the tracheobronchial wall.

See **Table 1.** below for a detailed summary of the characteristics of the subject device - *BroncTru Transbronchial Access Tool* compared to the predicate device – the Covidien LLC's *CrossCountry™ Transbronchial Access Tool* cleared in 510(k) [K142934], and to the referenced device – the Broncus Medical Inc. *LungPoint™ Tool* (LungPoint Sheath and LungPoint Dilation balloon) cleared in 510(k) [K131234].

**Table 1. Comparison of the BroncTru Transbronchial Access Tool to Predicate Device and Reference device:**

| **Device Name/ Characteristics** | **BroncTru Access Tool (Subject device) K232601** | **CrossCountry™ Transbronchial Access Tool (Predicate device) K142934** | **LungPoint Tools (Reference device) K131234** | **Comment** |
|---|---|---|---|---|
| Manufacturer | Broncus Medical Inc., San Jose, CA. | Covidien LLC., | Broncus Medical Inc., San Jose, CA. | |
| Device Classification | Class II | Class II | Class II | Same |
| Regulation Number | 874.4680 | 874.4680 | 874.4680 | Identical |
| FDA Product Code | EOQ | EOQ | EOQ | Same |

| Device Name/ Characteristics | BroncTru Access Tool (Subject device) K232601 | CrossCountry™ Transbronchial Access Tool (Predicate device) K142934 | LungPoint Tools (Reference device) K131234 | Comment |
|---|---|---|---|---|
| | **Technological Characteristics** | | | |
| Components | Aspiration Needle, Dilator, Sheath, Handle | Wire, catheter | LungPoint Sheath and Dilation Balloon | Some difference |
| Single Use | Yes | Yes | Yes | Same |
| Anatomical Location | Lung | Lung | Lung | Same |
| Introduction into the body | Endobronchial | Endobronchial | Endobronchial | Same |
| Sharp Distal Tip | Yes - Needle | Yes - Wire | Not known | Some difference |
| Radiopaque distal end | Yes | Yes | Yes | Same |
| Dilation Ability | Yes (Dilator) | Yes (Catheter) | Yes (balloon) | Same principle |
| Dilation Mechanism | Mechanical | Mechanical | Pneumatic | Same with predicate |
| Working Outer Diameter of components (mm) | Sheath: 1.92, 2.70mm<br>Dilator: 1.51, 2.16 mm | Catheter OD: 2.01mm<br>Wire OD: 0.66mm | Sheath: 2.65 mm<br>Balloon: 1.0 (uninflated)<br>4 mm (inflated) | Some difference |
| Working Channel Compatibility (mm) | ≥2.0 & ≥2.8 mm | ≥3.0 mm | Unknown | SE |
| Working Length (cm) | Catheter: 91.0 cm<br>Sheath: 90.0 cm | Catheter:109.9 cm<br>Wire: 116.1 cm | Sheath: 90 cm<br>Balloon: 97.5 cm | SE |
| Tip Diameter (mm)<br>Needle/Wire | 0.55, 0.6, 0.7 (Needle)<br>24G, 23G & 22G | Catheter: Tapers down to slightly larger than the wire -Wire: 0.41. | Not applicable | Some difference |
| Sterile/Single Use | Yes | Yes | Yes | Same |
| Sterilization Method | Ethylene Oxide | Ethylene Oxide | Ethylene Oxide | Same |
| Packaging | Needle assembly and syringe placed in tray with snap downs and Tyvek lid. Tray placed in shelf box prior to sterilization. | Needle assembly and syringe placed in tray with snap downs and Tyvek lid. Tray placed in shelf box prior to sterilization. | Needle assembly and syringe placed in tray with snap downs and Tyvek lid. Tray placed in shelf box prior to sterilization. | Same |
| Shelf-life Claim | 3-years | Unknown | 3-Years | Same |
| | **Materials That Come Into Contact With Patient** | | | |
| Sheath material | PTFE/PEBAX | Unknown (Polymer – Copolyester Elastomer) | PEBAX/Polyamide | Same with Reference device. |
| Dilator/Catheter Material | LDPE/HDPE | LDPE/HDPE (Catheter) | NYLON (Balloon) | Same material as predicate |
| Needle/Wire Material | Nitinol | Titanium/Nitinol | Nitinol | Same |

| Device Name/ Characteristics | BroncTru Access Tool (Subject device) K232601 | CrossCountry™ Transbronchial Access Tool (Predicate device) K142934 | LungPoint Tools (Reference device) K131234 | Comment |
|---|---|---|---|---|
| | **Intended Use and Indication for Use** | | | |
| Intended Use | Providing a channel which allows for subsequent endoscopic tool placement. | Providing a channel which allows for subsequent endoscopic tool placement. | Providing a channel which allows for subsequent endoscopic tool placement. | Same |
| Indication for Use | The BroncTru Transbronchial Access Tool is indicated for use in conjunction with a flexible bronchoscope to puncture the lung, dilate, and establish a working channel, facilitating the guidance of other endoscopic tools to reach target lesions. | 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. | The LungPoint Tools are endoscopic tools used with bronchoscopes and intended to be used as accessories to the LungPoint Software to aid in reaching a targeted area within the respiratory organs. | SE |
| Use Condition | Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope. | Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope | Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope. | Same |

**Conclusion:**

The Subject device, Broncus Medical Inc., *BroncTru Transbronchial Access Tool* is substantially equivalent to the Covidien LLC's *CrossCountry™ Transbronchial Access* Tool cleared in 510(k) Number K142934 and to the Reference device - the Broncus Medical Inc *LungPoint™ Tool* (LungPoint Sheath and LungPoint Dilation balloon) cleared in 510(k) [K131234] as they have the same: operating principles, technological characteristics, materials (except the Sheath material), sterilization method, intended use and indication for use. The four (4) non-significant differences between the subject device *BroncTru Transbronchial Access Tool*and predicate device *CrossCountry™ Transbronchial Access* Tool and to the Reference device - *LungPoint™ Tool* (LungPoint Sheath and LungPoint Dilation balloon) are listed below. They are:

- The subject device *BroncTru Transbronchial Access Tool* is comprised of Dilator, Sheath, puncture needle mounted on a catheter and a handle. While the predicate device - *CrossCountry Transbronchial Access Tool* is comprised of a wire and a catheter.

- The predicate device *CrossCountry Transbronchial Access Tool* incorporates a sharp nitinol wire tip for puncture of the tracheobronchial wall while the Subject device *BroncTru Tool* uses Nitinol needle to puncture the tracheobronchial wall).
- The predicate - *CrossCountry Transbronchial Access Tool* wire tip diameter is 0.41mm, while the subject device BroncTru Tool needle tip diameters are: 0.55, 0.6, 0.7 mm (24G, 23G and 22G needle gauges).
- Like the predicate - *CrossCountry Transbronchial Access Tool,* the subject device - *BroncTru Transbronchial Access Tool* dilates the created hole in the tracheobronchial wall using mechanical pressure. The subject device *BroncTru Transbronchial Access Tool* dilates the created hole in the tracheobronchial wall using a plastics Dilator, while the predicate device - *CrossCountry Transbronchial Access Tool* uses the catheter to dilate. The Reference device - *LungPoint Tools* dilates using pneumatic pressure (a dilation balloon).

These are all minor changes which do not alter or constitute a change to the technological characteristics, intended use, safety or principle of operation of the cleared predicate device *CrossCountry™ Transbronchial Access* Tool cleared in 510(k) Number K142934 and the Reference device - *LungPoint™ Tool* (LungPoint Sheath and LungPoint Dilation balloon) cleared in 510(k) [K131234].

A risk assessment of the effect of these changes confirms that these minor differences do not raise any new issues of safety and effectiveness. Hence a substantial equivalency of the subject device - *BroncTru Transbronchial Access Tool* to the predicate device - *CrossCountry™ Transbronchial Access* Tool is claimed.

## 5. PERFORMANCE DATA

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

### a. Biocompatibility Data:

Biocompatibility testing of the subject device *BroncTru Transbronchial Access Tool* was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1:2009, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The following tests were completed:

- Cytotoxicity
- In Vitro Hemolysis
- Sensitization
- Intradermal Reactivity Test
- Acute Systemic Toxicity
- Pyrogen Study

The above-named tests were performed with acceptable results for the *BroncTru Transbronchial Access Tool*. The Biocompatibility evaluation was performed to the Standards listed below. These tests were used to demonstrate that materials used for the design and manufacture of the subject device *BroncTru Transbronchial Access Tool* –

especially those materials that come in contact with patients, are biocompatible.

**Table 2. List of Standards used for the biocompatibility evaluation of the BroncTru Transbronchial Access Tool**

| Standard # | Title | Result |
|---|---|---|
| ISO 10993-1: 2018 | Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing within a Risk management Process | Pass |
| ISO 10993-2:2006 | Biological evaluation of medical devices-Part 2: Animal welfare requirements | Pass |
| ISO 10993-5: 2009 | Biological Evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity (MTT Method) | Pass |
| ISO 10993-4: 2017 | Biological Evaluation of medical devices -- Part 4: Selection of Tests for Interactions with Blood (Rabbit Blood) | Pass |
| ISO 10993-10: 2021 | Biological Evaluation of Medical Devices -- Part 10: Tests for irritation and Skin Sensitization (Extraction Method) | Pass |
| ISO 10993-10: 2021 | Biological Evaluation of Medical Devices -- Part 10: Tests for irritation and Skin Sensitization (Guinea Pig Maximization) | Pass |
| ISO 10993-11: 2017 | Biological Evaluation of Medical Devices -- Part 10: Tests for Systemic Toxicity (Extraction Method). | Pass |
| ISO 10993-11: 2017 | Biological Evaluation of Medical Devices -- Part 10: Tests for Systemic Toxicity (Extraction Method). Material-mediated Pyrogens Test | Pass |
| ISO 10993-7: 2010 | Biological Evaluation of Medical Devices -- Part 7: Ethylene Oxide Sterilization residuals | Pass |
| ISO 10993-12: 2021 | Biological Evaluation of Medical Devices --Part 12: Sample Preparation and Reference Materials | Pass |
| ISO 10993-23: 2021 | Biological evaluation of medical devices — Part 23: Tests for irritation | Pass |
| USP General Chapter <151> | Pyrogen Test | Pass |
| USP 42, NF 37, General Chapters <85> | Bacterial Endotoxins Test | Pass |
| USP 42, NF 37, General Chapters <161> | Medical Devices-Bacterial Endotoxin and Pyrogen Tests | Pass |

**b. Sterilization/shelf-life testing summary:**

Sterilization/shelf-life testing for the *BroncTru Transbronchial Access Tool* was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile". The proposed *BroncTru Transbronchial Access Tool* meets the requirements of ISO 11135-1:2014 "Sterilization of health care products – Ethylene oxide -- Part 1: Medical devices requirements for development, validation and routine control of a sterilization process for medical devices". This product's Ethylene oxide (EO) sterilization cycle is validated to achieve a minimum sterility assurance level (SAL) of 10-6. The product Ethylene oxide residual levels conform to ISO 10993-7:2008 (R:2012) "Biological Evaluation of Medical Devices- Part 7: Ethylene Oxide Sterilization Residuals". For detailed

information, **see Section 4 – Sterilization** for the Protocols and Results.

**c. Shelf-life testing summary:**

The Accelerated aging test for the *BroncTru Transbronchial Access Tool* was conducted in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. A 3-year accelerated aging test was performed. A three-year real-time test to demonstrate longer stability and support the results of the accelerated aging test is initiated.

**d. Bench testing summary:**

Bench testing for the *BroncTru Transbronchial Access Tool* as listed below was conducted to

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

**e. Usability study:**

Usability requirements of the *BroncTru Transbronchial Access Tool* are identified in D-28-11 Customer Requirements document according to IEC 62366.

Also, Broncus has identified user interface characteristics related to safety and potential use in Risk Management, with description and evaluation of the hazardous situation according to IEC 62366.

**f. Performance testing – Animal Study**

No animal study was performed to demonstrate substantial equivalence.

**g. Performance testing - Clinical**

No clinical study was performed to demonstrate substantial equivalence.

**6. RISK ANALYSIS SUMMARY**

A Risk analysis for the *BroncTru Transbronchial Access Tool* was conducted in accordance with established in-house Procedure S0013 and acceptance criteria based on ISO 14971:2019 +A11_2021 - Risk Management of Medical Devices and

AAMI/ISO TIR24971:2020 - Medical devices— Guidance on the application of ISO 14971:2019. The design verification tests, and their acceptance criteria were identified and performed as a result of this risk analysis assessment. The *BroncTru Transbronchial Access Tool* risk analysis report does show that there are no new risks or increase in the level of already established risks of the predicate device. The risks associated with the use of the *BroncTru Transbronchial Access Tool* have been reduced to as far as possible and the benefits of use of the device outweigh the risks associated with its use.

## 7. CONSENSUS STANDARDS AND OTHER STANDARDS APPLIED.

The following standards have been applied to the *BroncTru Transbronchial Access Tool*:

- AAMI/ANSI/ISO 10993-5: 2009
- ISO 10993-1: 2018
- ISO 10993-10: 2021
- ISO 10993-11: 2017
- ISO 10993- 4: 2017
- ISO 10993- 5: 2009
- ISO 10993-7: 2008+Cor1
- ISO 11135: 2014
- ISO 11607-1: 2019
- ISO 11607-2: 2019
- ASTM F1980-16
- ASTM F2063-05
- IEC 62366-1:2015
- ISO 15233-1:2021
- ISO 14971: 2019 +A11_2021
- AAMI/ISO TIR24971:2020 - Medical devices— Guidance on the application of ISO 14971:2019**.**

## 8. CONCLUSION.

Based on the indications for use, technological characteristics comparison, performance testing and risk-benefit profile to the predicate device, the Proposed device *BroncTru Transbronchial Access Tool* raises no new issue of safety and effectiveness. Therefore, the *BroncTru Transbronchial Access Tool* is substantially equivalent to the predicate device.