December 28, 2020

Insung Medical Co., Ltd.
% Dongha Lee
Regulatory Affairs Consultant
KMC,Inc.
Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu
Seoul, 08375
Korea, Republic Of

Re: K200968
Trade/Device Name: ANKOR Endobronchial Tube
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: November 23, 2020
Received: November 27, 2020

Dear Dongha Lee:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200968

Device Name
ANKOR endobronchial tube

Indications for Use *(Describe)*
This device is intended for use in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation.
The Endobronchial tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.

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.

510(k) SUMMARY

This summary of 510(k) –safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Nov. 23, 2020

1. INFORMATION

1.1 Submitter Information

- Submitter Name: INSUNG MEDICAL CO., LTD.
- Address
  : 168, GIEOPDOSI-RO, JIJEONG-MYEON, WONJU-SI, GANGWON-DO, 26354, KOREA
- Telephone Number: +82-70-5077-0118 ▪ Fax: +82-33-812-3010

1.2 Contact Person

- Name: Milly (Consultant / KMC, Inc.)
- Address: Room no. 1709, 123, Digital-ro 26-gil, Guro-gu, Seoul, 08390, Korea
- Telephone Number: +82-70-8965-5554 ▪ Fax: +82-2-2672-0579
- E-mail: milly@kmcerti.com

2. DEVICE INFORMATION

- Trade Name / Proprietary Name : ANKOR endobronchial tube
- Model : ABC33L, ABC35L, ABC37L, ABC39L, ABC33R, ABC35R, ABC37R, ABC39R HBC33L, HBC35L, HBC37L, HBC39L, HBC33R, HBC35R, HBC37R, HBC39R
- Common Name : Endobronchial Double lumen tube
- Classification Name : Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)
- Product Code : CBI
- Classification Regulation : 21CFR 868.5740
- Device Class : Class II
- Classification Panel : Anesthesiology

3. PREDICATE DEVICE

Predicate Device	
Manufacturer	Teleflex Medical
Device Name (Trade Name)	Sheridan Endobronchial Tubes
510(k) Number	K180253

4. SUBJECT DEVICE DESCRIPTION

ANKOR Endobronchial tube is consisted with double lumen tube with the body including 3 cuff (Bronchus Cuff, Trachea Cuff and ANKOR Cuff) / 2 cuff (Bronchus Cuff and Trachea Cuff), the stylet and elbow connector in order to separate connector for isolating and ventilating one lung during surgical procedures. The different point, between ABC Model and HBC Model, is whether ANKOR Cuff is consisted.

ANKOR Cuff, which is a part of the ABC Model only, takes to check correct insertion of the catheter.

When user is lack of the experience or is not confidence with operation, ABC Model is intended to use.

When the suction is necessary, this device can be possible to be assemble with suction catheter which is 10Fr or 12Fr with PVC (Listing Number: D422226) and this device is packaged with these suction catheter (Listing Number: D422226).

The device is made of silicone as a main material and is available in 33Fr to 39Fr depending on the patients who is requiring one-lung isolation under OR and ICU including Non-MR Environment only.

5. INTENDED USE

This device is intended for use in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation.
The Endobronchial tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.

6. SUBSTANTIAL EQUIVALENCE

ANKOR endobronchial tube is substantially equivalent to the predicate device (Endobronchial Tube; K180253). The following table is presented to demonstrate substantial equivalence.

S: Same, D: Different

-	Subject Device	Predicate Device (K180253)	S/D
Classification Name	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)	S
Product Code	CBI	CBI	S
Regulation Number	21CFR 868.5740	21CFR 868.5740	S
Indications for Use	This device is intended for use in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation. The Endobronchial tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.	This device is intended for use in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation. The Endobronchial tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.	S
Environments of Use	Hospital - OR and ICU	Hospital - OR and ICU	S
Direction for Use	Prescription Use	Prescription Use	S
Intended User	Trained Physicians	Trained Physicians	S
Patient Population	Patients requiring one-lung isolation	Patients requiring one-lung isolation	S

Design Features	Lumen Shaft, Cuffs, Stylet	Lumen Shaft, Cuffs, Stylet	S
Sizes (Fr; French)	33 to 39 French	28 to 41 French	D
Cuffed	Yes	Yes	S
Radiopaque	Yes	Yes	S
Connection to ventilation source	15mm Connector	15mm Connector	S
Single use	Single use	Single use	S
Sterilization (Method)	Yes (EO Gas)	Yes (EO Gas)	S
EO and ECH Residual	The ethylene oxide residual is conform to ISO 10993-7	The ethylene oxide residual is conform to ISO 10993-7	S
Package	Sterile, packed with Elbow connector and suction catheter	Sterile, packed with connector	D
Biocompatibility	Cytotoxicity Test (ISO 10993-5) Sensitization Test (ISO 10993-10) Irritation Test (ISO 10993-10) Particulate Matter Test (ISO 18562-2:2017) Volatile Organic Compound Extraction Test (ISO 18562-3:2017)	Cytotoxicity Test (ISO 10993-5) Sensitization Test (ISO 10993-10) Irritation Test (ISO 10993-10) Particulate Matter Test (ISO 18562-2:2017) Volatile Organic Compound Extraction Test (ISO 18562-3:2017)	S
DLT Materials	Silicon	PVC	D

1) Same points between the subject device and the predicate device

- Classification Name

  : The proposed classification name of the subject device is “Tracheal/bronchial differential ventilation tube”. It is the same classification name both subject device (ANKOR Endobronchial Tube) and the predicate device (K180253).

- Product Code

  : The proposed product code of the subject device is “CBI”. It is the same product code both subject device (ANKOR Endobronchial Tube) and the predicate device (K180253).

- Regulation Number

  : The regulation number, which is applied to the subject device, is “21CFR868.5740”. It is the same regulation number both subject device (ANKOR Endobronchial Tube) and the predicate device (K180253).

- Indications for Use

  : The indications for use is “This device is intended for use in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation. The Endobronchial tube is indicated for main stem bronchus intubation and allows for selective inflation or deflation of either lung.” under both devices (Subject device and predicate device). It is same point.

- Environment of Use

  : For environment of use, both devices (subject device and predicate device) is used at hospital in order to safely use the both. It is same point.

- Direction for use

  : Both devices are prescription used device. It is same point.

- Intended User

  : For intended user, trained physicians shall use the both device in order to safely use the both. It is same fact.

- Patient Population

  : Bothe device is used for patients requiring one-lung isolation as the patient population in thoracic surgery, bronchospirometry, administration of Endobronchial anesthesia and other uses commonly requiring Endobronchial intubation. It is same point.

- Design Features

  : Under the main body of both devices, the design features are consisted with lumen Shaft, Cuff and Stylet. It is same point.

- Single use

  : Both devices (subject device and predicate device) is single used device which is E.O. Gas Sterilize. It is same point.

- Cuffed

  : Both devices have cuffs such as bronchial cuff and tracheal cuff to block the bronchial or tracheal for isolating and ventilating one lung during surgical procedures. It is same point.

- Radiopaque line

  : Under the tube (catheter) of both devices, the tubes contain an x-ray opaque line that runs through the tube making them detectable by x-ray. It is same point.

- Connection to ventilation source

  : 15mm Connector is used under both devices (subject device and predicate device). The connector could be possible to assemble with ventilation source. It is same point.

- Single use

  : Both devices (subject device and predicate device) is single used device which is E.O. Gas Sterilize. It is same point.

- Sterilization (Method)

  : Both devices (subject device and predicate device) are single used devices which are E.O. Gas Sterilize. It is same point.

- EO and ECH Residual

  : EO Gas Residual of Both devices (subject device and predicate device) are confirmed in accordance with ISO 10993-7. It is same point.

- Biocompatibility

  : General Biocompatibility Tests of both devices (subject device and predicate device) are selected in accordance with ISO 10993-1. The same tests, such as following, are conducted.

Test Item	Standard
Cytotoxicity Test	ISO 10993-5:2009
Sensitization Test	ISO 10993-10:2010
Irritation Test	ISO 10993-10:2010

In addition, both device could be possible to be connected with breathing gas supplier.
In accordance with “Biocompatibility of breathing gas pathway (ISO 18562-1:2017)” which considers risk related to breathing gas pathway, Particulate Matter Test (Per ISO 18562-2:2017) including CO, CO2 and O3 (Ozone) and Volatile Organic Compound Extraction Test (Per ISO 18562-3:2017) are conducted additionally to assure biocompatibility of subject device.
It leads the subject device is more safety than predicated device that is not assured on the “Biocompatibility of breathing gas pathway”.

2) Different points between the subject device and the predicate device

- Size

  : Although size of the subject device is different with size of predicate device, the subject device is verified by test such as appearance test, dimension test.

  And, the subject device is placed on the CE market and Korean Market since 2013 years. As a result, any problems, which influence safety and performance of the subject device, are not founded and received through the customer feedback.

  In addition, the size of predicated device includes size of the subject device.

  We cannot also found any risks related to the subject device, which has same size with subject device. It leads to safety device and effectiveness size to achieve same indication for use.

  Refer to Performance Test Report (IS-20-1026-2) on the Attachment 6

- Package

  : Packaging composition is different. It is depending on the manufacturer.

  In addition, elbow connector of subject device complies with the ISO 5356-1:2014 and suction catheter is complies with the ISO 8836:2014 to ensure the safety and performance. The result of the test is passed and it leads to ensure the safety and performance.

  As a result, there are not any problems, which influence safety of the subject device as well as influence substantial equivalence between the subject device and predicate device.

  Refer to Performance Test Report (IS-20-0710) on the Attachment 6

- Materials

  : As a different point on the material between the subject device and predicate device, there is DLT Materials such as Silicon (Subject device) and PVC (Predicate Device)
  Although the subject device is different with predicate device, the subject device is verified by test such as a biocompatibility test according to ISO 10993-1, ISO 18562 and FDA Guidance ("Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"). And, the endotoxin test is conducted in accordance with USP 39 <85> to ensure safety of the materials.
  As a result, there are not any problems, which influence safety of the subject device as well as influence substantial equivalence between the subject device and predicate device.

Refer to Biocompatibility Test with on the Attachment 1 and Attachment 2

Test	Report No.	Attachment No.
Bacterial Endotoxin Test	20-048384-01-1	1
Biocompatibility Test (Per ISO 10993-1)	MTK-012652 MGK-201900654 MGK-2019-000089 MGK-2019-000088	1
Biocompatibility Evaluation Report (Per ISO 18562-1:2017)	1001018172-3248567BA	2
ISO 18562-2:2017 Test	1001018172-3248568P	2
ISO 18562-3:2017 Test	1001018172-3248567	2

3) Comparison to predicate device

The subject device is substantially equivalent to the predicate device with respect to indications for use, technology and construction. The differences between the predicate and the subject device is minor and any risks have been mitigated through testing.

7. PERFORMANCE DATA

All testing that is required by the required standards has been performed. Non-clinical testing was performed and included standards such as ISO 16628, ISO 5356-1, ISO 5361, ISO 80369-7, ISO 8836, ISO 18562 and ISO 10993-1. The Endobronchial Tube have been found to fall within the required limits of the testing. The test results can be found in both the Biocompatibility and the Performance Testing of this submission. Therefore we have concluded that the subject device is substantially equivalent. A brief summary of tests relied upon to demonstrate substantial equivalence to the predicate can be found in the below:

7.1 Biocompatibility

1) General Biocompatibility (According to ISO 10993-1)

The biocompatibility tests were performed to protect patients from undue risks arise from biological hazards associated with materials of manufacture and final device. The tests were performed in accordance with the following standards and FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

No.	Test Items	Standards	Criteria	Pass/Fail
1	Cytotoxicity	ISO 10993-5:2009	Negative Control: reactivity of none Positive Control: greater than mild	Pass
2	Intracutaneous Reactivity	ISO 10993-10:2010	No observe skin responses such as the erythema, edema and etc.	Pass
3	Sensitization	ISO 10993-10:2010	No induced any skin reaction in the Hartley guinea pig	Pass

Refer to Biocompatibility Test with on the Attachment 1

Test	Report No.	Attachment No.
Biocompatibility Test (Per ISO 10993-1)	MTK-012652 MGK-201900654 MGK-2019-000089 MGK-2019-000088	1

2) Biocompatibility of Breathing Gas Pathways (ISO 18562-1)

Biocompatibility evaluation of breathing gas pathways is performed in accordance with ISO 18562-1:2017 including ISO 10993-17:2002 to identify which compounds emitted into the airstream of the Endobronchial Double Lumen Tube (ANKOR Endobronchial Tube) are considered chemicals of concern (COCs) and require additional risk review.

No.	Test Items	Standards	Criteria	Pass/Fail
1	Emission Test of Particulate Matter (Including CO2, CO and Ozone)	ISO 18562-2:2017	No increase the source gas concentration of particulates ≤2.5 μm aerodynamic diameter (PM2.5) more than 12 μg/m3	Pass
			No increase the source gas of PM ≤ 10 μm diameter size (PM10) more than 150 μg/ m3	Pass
2	Volatile Organic Compounds (VOCs) Extraction Test	ISO 18562-3:2017	Unlikely to result in toxicological effects	Pass

Refer to Biocompatibility Test with on the Attachment 2

Test	Report No.	Attachment No.
Biocompatibility Evaluation Report (Per ISO 18562-1:2017)	1001018172-3248567BA	2
ISO 18562-2:2017 Test	1001018172-3248568P	2
ISO 18562-3:2017 Test	1001018172-3248567	2

7.2 Risk Management

All risks, related to biocompatibility hazard, function hazard and etc., including device problem founded by TPLC (Total Product Life Cycle)., were identified, evaluated, and controlled in accordance with ISO 14971:2007.

No.	Items	Standards	Attachment No. (Report No.)
1	Risk Management	ISO 14971:2007	Attachment 4 (IM-RMR-09) (IS-RMR-202)

7.3 Sterilization Test

The sterilization test was performed to assess inactivation of the microbiological contaminants, and thereby the device the device is verified as a non-sterile medical device into sterile ones. The tests were performed in accordance with following standards.

No.	Test Items	Standards	Attachment No. (Report No.)
1	Microbiological quality	ISO 11737-1:2018	Attachment 10 (IS-SVP-1901) (IS-SVR-02)
2	Sterility Test	ISO 11737-2:2009	Attachment 10 (IS-SVP-1901) (IS-SVR-02)
3	E.O. Gas Sterilization Residuals	ISO 10993-7:2008	Attachment 10 (IS-SVP-1901) (IS-SVR-02)

7.4 Cleanroom Validation

Clean rooms are managed by being based on our work environment management regulations. Clean rooms validation is assured through the verification of clean room validation in accordance with verification method for subject device’s safety an hygienically.

No.	Test Items	Standards	Attachment No. (Report No.)
1	Particle Test	ISO 14644-1:2015	Attachment 11 (IS-CVP-01) (IS-CVR1-01)

7.5 Cleaning Validation

Contaminants and residues during the cleaning process were maintained continuously and consistently with acceptable numerical values through the appearance test according to manufacturer SOP and microbial test according to ISO 11737-1:2018

No.	Test Items	Standards	Attachment No. (Report No.)
1	Appearance Test	Manufacturer SOP	Attachment 11 (IS-WVR-02)
2	Microbial Test	ISO 11737-1:2018	Attachment 11 (IS-WVR-02)

7.6 Shelf-life Test

The shelf-life test was performed to decide expiration date and to assess a stability of physical properties of their packaging materials within the duration of the proposed shelf-life. The tests were performed in accordance with following standards.

No.	Test Items	Standards	Criteria	Pass/Fail	Attachment No. (Report No.)
1	Accelerated Aging Test	ASTM F 1980	3 years	Pass	Attachment 12 (MSK-000970)

According to ISO 11607-1, sterile barrier system and packaging system are established and maintained. The maintenance of this system has been validating for patient safety according to ISO 11607-2

No.	Test Items	Standards	Criteria	Pass/Fail	Attachment No. (Report No.)
1	Seal Strength	ASTM F88:2000	≥1.2(Unit: N/15mm) (After 3years Accelerated aging device)	Pass	Attachment 12 (MSK-000970)
2	Sterile Barrier System Integrity (Dye Penetration)	ASTM F1929	No leakage	Pass	Attachment 12 (MSK-000970)
3	Sterility Test	KP	No evidence of microbial growth	Pass	Attachment 12 (MSK-000970)

7.7 Endotoxin Test

Bacterial Endotoxin Test (Kinetic), using the lysate reagent for Endobronchial Double Lumen Tube, was conducted in accordance with USP 39 <85> including USP <161> and "Guidance for industry pyrogen and endotoxin testing: Questions and Answers".

Therefore, the endotoxin concentration of the test article extract used in the test was decided to be less than 0.5 EU/mL.

No.	Test Items	Standards	Criteria	Pass/Fail	Attachment No. (Report No.)
1	Bacterial Endotoxin Test	USP 39 <85>	< 0.5EU/mL	Pass	Attachment 1 (20-048384-01-1)

7.8 Performance Test

The following tests were performed to assess effectiveness of the product performance. The tests were performed in accordance with following standards.

No.	Test Items	Standards	Criteria	Pass/Fail	Attachment No. (Report No.)
1	Dimension Test	ISO 16628:2008	Outside diameter of bronchial segment : Express the results in milimetres, as determined, to one decimal place, rounded up to the nearest 0.5mm Effective inside diameter: The determined dimension is expressed in millimetres rounded to the nearest 0.2mm.	Pass	Attachment 6 (IS-20-1026-2)
2	Colour Coding	ISO 16628:2008	Bronchial cuff and pilot balloon colour blue	Pass	Attachment 6 (IS-20-1026-2)
3	Segment Differentiation	ISO 16628:2008	When viewed from the end of the machine, it must be clearly distinguishable from each other.	Pass	Attachment 6 (IS-20-1026-2)

2	Tensile Strength	N/A	When pulling for 15 seconds with a force of not less than 15 N in the longitudinal direction, except for removable connections such as connectors, there shall be no damage to the connection. (Korean Ministry of Food and Drug Safety Standards)	Pass	Attachment 6 (IS-20-1026-2)
3	Cuff Leakage Test	N/A	There should be no leakage when put into the water.	Pass	Attachment 6 (IS-20-1026-2)
4	Connector Bonding Strength	ISO 5356-1:2014	Hold the connector and tube vertically and do not separate from a force of 15 N or less when pulled.	Pass	Attachment 6 (IS-20-1026-2)
5	Cuff Resting Diameter	ISO 5361:2016	At a pressure of 2 kPa the cuff diameter shall be as follows. within ± 0.5 mm of the nominal value when tested in accordance with ISO 5361 Annex B.	Pass	Attachment 6 (IS-20-1026-2)
6	Tube Collapse	ISO 5361:2016	The steel ball shall pass freely through the tube when tested according to ISO 5361 Annex C	Pass	Attachment 6 (IS-20-1026-2)
7	Cuff Herniation	ISO 5361:2016	No part of the inflated cuff shall reach beyond the nearest edge of the bevel when tested according to ISO 5361 Annex D	Pass	Attachment 6 (IS-20-1026-2)

8	Cuff burst pressure (Cuff Burst Evaluation)	N/A	Do not damage at 90cmH2O pressure	Pass	Attachment 6 (IS-20-1026-2)
9	Cuff Bond Pressure (Cuff Bond Strength)	N/A	ANKOR cuff : Must not be damaged at forces of 2.0 kgf or less. Bronchial cuff : Must not be damaged at forces of 1.0 kgf or less. Tracheal cuff : Must not be damaged at forces of 2.0 kgf or less.	Pass	Attachment 6 (IS-20-1026-2)
10	Bond strength testing of the joints of endobronchial tube	N/A	Do not damage at 90cmH2O pressure	Pass	Attachment 6 (IS-20-1026-2)
11	Liquid and Air leakage	ISO 80369-7:2016	No leakage sufficient to form a falling drop of water	Pass	Attachment 6 (20-048204-01-1)
12	Separation force of one way valve	ISO 80369-7:2016	The conical fitting under test remain attached to the test fixture	Pass	Attachment 6 (20-048204-01-1)
13	Stress cracking	ISO 80369-7:2016	There shall be no evidence of stress cracking of the conical fitting	Pass	Attachment 6 (20-048204-01-1)
14	Radiopaque Test	N/A	The outline shall be clearly visible when taken with the following conditions. Milliampere: 10MAS Tube Voltage: 65 to 70 KVP	Pass	Attachment 6 (IS-20-1026-2)

			Distance between focus and sample: 76.2 to 127 cm		
15	Dimension	ISO 8836:2014	1. Y-110 : O.D 3.33 ± 0.15mm / minimum ID 2.00mm 2. Y-112 : O.D 4.0 ± 0.15mm / minimum ID 2.45mm	Pass	Attachment 6 (IS-20-0710)
16	Security of construction of suction catheter (Tensile Strength)	ISO 8836:2014	The connector shall not damage the catheter connection at a force of at least 5 N.	Pass	Attachment 6 (IS-20-0710)
17	Shaft resistant to negative pressure of suction catheter	ISO 8836:2014	Even if the vacuum regulator is blocked, the shaft must be intact.	Pass	Attachment 6 (IS-20-0710)

8. Clinical Testing and Animal Testing

Clinical and animal testing were not performed for ANKOR Endobronchial Tube as part of the premarket notification requirements for this 510(k) submission and the subject of this premarket submission, ANKOR Endobronchial Tube, did not require clinical and animal studies to support substantial equivalence.

9. CONCLUSION

Under the comparing substantial equivalence between the subject device (ANKOR Endobronchial Tube) and the predicate device (Endobronchial Tube; K180253), there are the same points such as product code, indications for use, mechanism and structure.
Although there are some differences (Size, Package and Raw Material), the performance data are supported to the safety and effectiveness of the subject device.
In this regard, we conclude that the subject device is substantially equivalent to the predicate device.