DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 10, 2016

Henan Tuoren Medical Device Co., Ltd
C/O Long Yang
COO
Shenzhen Hlongmed Biotech Company
R15-08, East Building, Yihai Plaza, Chuangye Road,
Nanshan District, Shenzhen, Guangdong, 518054
China

Re: K152251
Trade/Device Name: Endobronchial Tube
Models: Left: Fr26, Fr28, Fr31, Fr32, Fr33, Fr35, Fr37, Fr39, Fr41;
Right: Fr26, Fr28, Fr31, Fr32, Fr33, Fr35, Fr37, Fr39, Fr41
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: May 6, 2016
Received: May 12, 2016

Dear Long Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152251

Device Name
Endobronchial Tube
Models: Left: Fr26, Fr28, Fr31, Fr32, Fr33, Fr35, Fr37, Fr39, Fr41; Right: Fr26, Fr28, Fr31, Fr32, Fr33, Fr35, Fr37, Fr39, Fr41

Indications for Use *(Describe)*
The Endobronchial Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

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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Henan Tuoren Medical Device Co., Ltd

510(k) Summary

(as required by 807.92(c))

The assigned 510(K) number is: K152251

Date of Summary: June 9, 2016

1. Submitter information

Manufacturer Name: Henan Tuoren Medical Device Co., Ltd

Address: Weiyuan Industrial Zone, Menggang ,Changyuan Country, Henan, China

Establishment Registration Number: 3006984712

Contact Person and Title: Meizi Zhang/Manager of Registration Department

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2. Contact person

2.1 Primary Contact Person

Long Yang (COO)

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2.2 Secondary Contact Person

Meizi Zhang(Manager of Registration Department)

Henan Tuoren Medical Device Co., Ltd

Tel: 0086-13633736073

3. Device Classification

Device Sponsor	Henan Tuoren Medical Device Co., Ltd

Trade/Device Name	Endobronchial Tube
Model	Left: Fr26, Fr28, Fr31, Fr32, Fr33, Fr35, Fr37, Fr39, Fr41 Right: Fr26, Fr28, Fr31, Fr32, Fr33, Fr35, Fr37, Fr39, Fr41
Common Name	Endobronchial Double Lumen Tube
Classification Name	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)
Regulatory Class	Class II
Classification regulation	21CFR 868.5740
Review Panel	Anesthesiology
Regulation Medical Specialty	Anesthesiology
Regulation Name	Tracheal/bronchial differential ventilation tube
Product Code	CBI

4. Intended Use/ Indications for Use

The Endobronchial Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

5. Predicate Device

Well LEAD Endobronchial Tubes(K092886)

6. Device Description

The Endobronchial Tube is made of Polyvinylchloride and is available in sizes 26fr to 41fr. They are designated as double lumen tube with 2 cuffs and separate 15mm connectors for isolating and ventilating one lung during surgical procedures. The tubes contain an x-ray opaque line that runs through the tube making them detectable by x-ray. Environments of use: Hospital-OR and ICU

7. Substantial Equivalence

Henan Tuoren Medical Device Co., Ltd claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in K092886. Henan Tuoren Medical

Device Co., Ltd claims this equivalence because the proposed devices have an equivalent intended use, manufacturing materials, operating principles and physical operational specifications as compared to the predicate devices. The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix, the comparison matrix can be referred to the below table. The differences between subject device and the predicate device is just the size and packaging, these differences do not effect substantial equivalence, the analysis and justification is: For the size differences, all models of proposed devices comply to the same standard ISO 5361 compared to predicate devices. For the packaging differences, the multi-functional joint of proposed device comply to the same standard ISO 5356-1 compared to predicate devices, and the suction catheters of proposed devices comply to the same standard ISO 8836 compared to predicate devices..

Item	Element Of Comparison	Proposed Device	Predicate Device	S/D*
1	Classification Name	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)	S
2	Regulatory Class	Class II	Class II	S
3	Classification regulation	21CFR 868.5740	21CFR 868.5740	S
4	Classification Panel	Anesthesiology	Anesthesiology	S
5	Product Code	CBI	CBI	S
6	Regulation Name	Tracheal/bronchial differential ventilation tube	Tracheal/bronchial differential ventilation tube	S
7	Indications for Use/Intended Use	Endobronchial Tubes is used to isolate the left or the right lung of a patient for surgery,one lung ventilation or one lung anesthesia.	The Well Lead Endobronchial Tubes is used to isolate the left or the right lung of a patient for surgery,one lung ventilation or one lung anesthesia.	S
8	Directions for Use	Prescription Use	Prescription Use	S
9	Patient Population	Patients undergoing surgical procedure requiring isolation of one lung	Patients undergoing surgical procedure requiring isolation of one lung	S
10	Patient contact Material	Tube-PVC and Cuff-PVC	Tube-PVC and Cuff-PVC	S
11	Size(Fr)	26 to 41 French	28 to 41 French	D, does not affect the product performance
12	Design Features	Double lumen shaft, 2 cuffs, Stylet, Carlens adapter	Double lumen shaft, 2 cuffs, Stylet, Carlens adapter	S
13	Composition of Endobronchial Tubes	main tube, cuff, connector, inflating tube, valve, pilot balloon	main tube, cuff, connector, inflating tube, valve, pilot balloon	S
14	Angle of bevel	70°	70°	S
15	Radius of curvature	140mm	140mm	S

*Note: S: same D: different

Item	Element Of Comparison	Proposed Device	Predicate Device	S/D*
16	Radiopaque line	Yes	Yes	S
17	Connection to ventilation source	15mm connector	15mm connector	S
18	Shelf-life	5 years	5 years	S
19	Single Use Single patient, disposable	Yes	Yes	S
20	Method of sterilization	Ethylene Oxide Sterilized per ISO 11135	Ethylene Oxide Sterilized per ISO 11135	S
21	The Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	S
22	EO and ECH residual	The ethylene oxide residual is conform to ISO 10993:7 for Limited Exposure Devices of 4mg/day for EO and 9/mg/day for ECH.	The ethylene oxide residual is conform to ISO 10993:7 for Limited Exposure Devices of 4mg/day for EO and 9/mg/day for ECH.	S
23	Biocompatibility	1.Cytotoxicity testing per 10993-5 2. Sensitization testing per ISO 10993-10 3.Irritation Test per ISO 10993-10 All the test passed.	1. Cytotoxicity testing per 10993-5 2. Sensitization testing per ISO 10993-10 3. Irritation Test per ISO 10993-10 All the test passed.	S
24	Applied Standards	ISO 5361 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 11135 ISO 10993-7	ISO 5361 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 11135 ISO 10993-7	S
25	Packaging	Sterile, packed with a multi-functional joint and three Suction Catheters	Sterile，packed with switch connector and two suction catheters	D, does not affect the product performance
26	Environments of use	Hospital-OR and ICU	Hospital-OR and ICU	S

*Note: S: same D: different

8. Product Performance Testing

All testing that is required by the required standards has been performed. Non-clinical testing was performed and included standards such as ISO 5361 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 (Section16) and the Performance Testing_Bench (Section19) of this submission. Therefore we have concluded that the Endobronchial Tube are substantially equivalent.

A brief summary of tests relied upon to demonstrate substantial equivalence to the predicate can be found in the table below:

1) Biocompatibility testing

Type of Test	**Referenced Standard**	**Test result**
in vitro cytotoxicity	ISO10993-5:2009	Under the conditions of using ISO10993-5: 2009 test method MTT method MEM extract, the test article Endobronchial Tube extract showed no potential toxicity to L-929 cells.
		Under the conditions of using ISO10993-5: 2009 test method MTT method MEM with 10% FBS extract, the test article Endobronchial Tube extract showed no potential toxicity to L-929 cells.
Skin sensitization Test using Guinea Pig Maximization test	ISO10993-10:2010	Under the conditions of using ISO10993-10: 2010 test methods guinea pig maximization test 0.9% sodium chloride injection extract, the test article Endobronchial Tube extract showed no significant evidence of causing skin sensitization in the guinea pig;
		Under the conditions of using ISO10993-10:2010 test methods guinea pig maximization test sesame oil extract, the test article Endobronchial Tube extract showed no significant evidence of causing skin sensitization in the guinea pig;

Type of Test	**Referenced Standard**	**Test result**
Oral Mucosa Irritation test	ISO10993-10:2010	Under the conditions of using ISO10993-10:2010 test methods 0.9% sodium chloride extract, the test result showed that the test article Endobronchial Tube extract show no significant evidence of causing oral irritation in the hamster.
		Under the conditions of using ISO10993-10:2010 test methods sesame oil extract, the test result showed that the test article Endobronchial Tube extract show no significant evidence of causing oral irritation in the hamster.

2) Performance Testing

Type of Bench Test	Reference standards	Acceptable Criteria	Pass/fail
cuff diameter	ISO 5361: 2012	The maximum cuff diameter shall be within ± 0.5mm of the nominal value when tested according to ISO 5361 Annex B	Pass
cuffed tube collapse test	ISO 5361: 2012	the steel ball shall pass freely through the tube when tested according to ISO 5361 Annex C	Pass
Cuff herniation test	ISO 5361: 2012	no part of the inflated cuff shall reach beyond the nearest edge of the bevel when tested according to ISO 5361 Annex D	Pass
Seal testing	ISO 5361: 2012	The leakage limit is ≤2.0ml/h at cuff pressures not to exceed 2,7 kPa (27 cmH_2O) when tested according to ISO 5361 Annex G	Pass
	/	Sealing of cuff inflating system: No air leakage happens under the condition of continuous 3kPa positive pressure imposition for 10 seconds	Pass
	/	Sealing of connector assembly: No air leakage happens on any joints under the condition of continuous 6kPa gas pressure imposition to lumen of main tube(shaft) for 60 seconds.	Pass

inflating tube	ISO 5361: 2012	The inflating tube shall have an outside diameter of not more than 3.0mm	Pass
	ISO 5361: 2012	The angle between the inflating tube and the Endobronchial tube at the point of separation shall not exceed 45°.	Pass
Kink resistance test	ISO 5361: 2012	the steel ball shall pass freely through the lumen of the tube when tested according to ISO 5361 Annex H	Pass
Gauging of One Way Valve	ISO 594/1 1986	The plane of the maximum diameter at the opening of the female conical fitting of One Way Valve lie between the two limit planes of the gauge.	Pass
Liquid leakage of One Way Valve	ISO 594/1 1986	no leakage sufficient to form a falling drop of water	Pass
Air leakage of One Way Valve	ISO 594/1 1986	Continued formation of air bubbles not be evident	Pass
Separation force of One Way Valve	ISO 594/1 1986	The conical fitting under test remain attached to the test fixture	Pass
Stress cracking	ISO 594/1 1986	There shall be no evidence of stress cracking of the conical fitting	
Security of construction of suction catheter	ISO 8836-2007	the force required to detach any component permanently attached to the shaft shall be not less than that specified in standard	Pass
Shaft resistant to negative pressure of suction catheter	ISO 8836-2007	a vacuum source at 40kPa below ambient pressure for 15s at a temperature of 23℃ ±2℃ with the patient end occluded, the shaft shall not collapse	Pass
15mm connector	ISO5356-1：2004	Comply with the ISO5356-1：2004	Pass
Burst Testing	/	Cuff burst: The volume of injected gas when cuff bursting happens is larger than 40ml during inflation of endobronchial tube bursting between cuff and main tube: There should be no fracture on junctions while inflated 30kpa gas.	Pass
Bond Strength	/	The joints of endobronchial tube should be firm bonding.When an axial force of 50±5N is applied at 50±5mm/min, the testing portion(between connector and	Pass

		tubing; between main tube and four-channel connector; between bronchial tube and four-channel connector; between tracheal tube and four-channel connector) should not depart from each other. When an axial force of 50±5N is applied at 50±5mm/min, the testing portion(between inflation line and main tube) should not depart from each other.	
Air flow resistance	/	Pressure increment should no more than 0.2Kpa/h when testing the endobronchial tube under the specified flow rate(3, 6, 9L/min)	Pass
Radiopaque test	/	When exposing the Endobronchial tube with the low dose rays, the X-ray machine should have film development.	Pass
Endotoxin test	USP36_NF31<85>	0.25EU/ml, 20EU/Device	Pass

9. Clinical Testing and animal testing

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

10. Substantial Equivalence Conclusion

The information provided in the 510(k) submission is sufficient to demonstrate the substantial equivalence of subject device to the predicate device.