January 17, 2018

Zhanjiang Star Enterprise Co., Ltd
% Jessie You
Official Correspondent
Shenzhen Joyantech Consulting Co., Ltd
Room 1122, No.55 Shizhou Middle Road
Nanshan District
Shenzhen, GD755 TW

Re: K170234
Trade/Device Name: Endotracheal Tube; Reinforced Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: November 15, 2017
Received: November 30, 2017

Dear Jessie You:

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.

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.

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,

Tara A. Ryan -S
2018.01.17 06:29:26 -05'00'

for
Tina Kiang, Ph.D.
Acting 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)*
K170234

Device Name
Endotracheal tube / Reinforced Endotracheal tube

Indications for Use *(Describe)*
The Endotracheal tube is intended for oral or nasal intubation and for airway management.
The Reinforced Endotracheal tube is intended for airway management by oral or nasal intubation of the trachea during anesthesia. It is a device inserted into the trachea through the mouth or nose to facilitate breathing and it may be used where the patient's neck is likely to be moved of flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.

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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VOL_006:001_510(k) Summary

1. Submission Sponsor

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Date Prepared	01/19/2017

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
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3. Devices Identification

Trade name	Endotracheal tube
Common name	Tracheal tube
Classification	II
Classification name	Tracheal tube
Regulation number	21 CFR 868.5730
Product code	BTR
510(k) review panel	Anesthesiology
Performance standards	The performance was evaluated in accordance with ISO 5361: 2012. Biocompatibility tests were done in conformance with relevant requirements of ISO10993.

Trade name	Reinforced Endotracheal tube
Common name	Tracheal tube
Classification	II
Classification name	Tracheal tube
Regulation number	21 CFR 868.5730
Product code	BTR
510(k) review panel	Anesthesiology
Performance standards	The performance was evaluated in accordance with ISO 5361: 2012. Biocompatibility tests were done in conformance with relevant requirements of ISO10993.

4. Legally Marketed Predicate Devices

Trade name	Disposable Tracheal Tube
Regulation number	21 CFR 868.5730
Regulation name	Tracheal tube
Regulatory class	II
510 (k) number	K140228
Product code	BTR
Manufacturer	Suzhou Weikang Medical Apparatus Co., Ltd

Trade name	BEVER™ Reinforced Endotracheal Tube
Regulation number	21 CFR 868.5730
Regulation name	Tracheal tube
Regulatory class	II
510 (k) number	K111406
Product code	BTR
Manufacturer	Hangzhou Bever Medical Devices Company, Limited

5. Device Description

The Endotracheal tubes are used for oral or nasal intubation and for airway management, which are mainly for patients that require repeated anesthesia, artificial ventilation and assisted breathing. The Endotracheal tube is available in cuffed and uncuffed variants. The cuff is intended to provide a seal against the trachea, ensuring that inspiratory and expiratory gasses are routed through the tube and not allowed to escape to the patient's upper airway. The structure of Cuffed Endotracheal tube contains a main tube (patient end, machine end and murphy eye), cuff, and inflating system (including inflating tube, valve and pilot balloon). The uncuffed Endotracheal tube contains main tube (patient end, shaft and machine end). All variants have a Murphy eye. The products are primarily made from polyvinyl chloride (PVC) materials. The Endotracheal tubes are available in a number of sizes: the nominal inside

diameter of uncuffed Endotracheal tubes are from 2.0mm to 10.0mm; the nominal inside diameter of cuffed Endotracheal tubes are from 2.5mm to 10.0mm. The Endotracheal tubes are disposable and are supplied sterile. The contact time should be no more than 30 days.

The reinforced Endotracheal tubes are a tracheal tube with additional metal wire spiral reinforcement to provide kink-resistance. The products are always used during operations where a high degree of flexibility is required from the tube. The reinforced Endotracheal tubes are also available in cuffed and uncuffed variants, and nominal inside diameter of both the uncuffed and cuffed reinforced Endotracheal tubes are from 3.0mm to 9.0mm. The only difference between reinforced Endotracheal tubes and Endotracheal tubes is the metal wire spiral inside the tube, which is made by 304 stainless steel and used for reinforcement that maintains the patency of the lumen.

6. Indications for Use Statement

The Endotracheal tube is intended for oral or nasal intubation and for airway management.

The Reinforced Endotracheal tube is intended for airway management by oral or nasal intubation of the trachea during anesthesia. It is a device inserted into the trachea through the mouth or nose to facilitate breathing and it may be used where the patient's neck is likely to be moved of flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.

7. Substantial Equivalence Discussion

Table 1: Substantial equivalence comparison between Endotracheal tube and Disposable Tracheal Tube.

Items	The proposed device-Endotracheal tube	The predicate device-Disposable Tracheal Tube K140228
Classification	II 21 CFR 868.5730 BTR	II 21 CFR 868.5730 BTR
Indications for use	The Endotracheal tube is intended for oral or nasal intubation and for airway management.	Disposable endotracheal tube is intended for oral or nasal intubation and for airway management.
Structure and composition	The uncuffed tube: 1. Main tube 2. Connector The cuffed tube: 1. Main tube 2. Cuff	The tracheal tube without a cuff: 1. Tubular body 2. Standard connector The cuffed tracheal tube: 1. Tubular body 2. Cuff

	3. Inflating system (contains inflating tube, valve and pilot balloon)	3. One-way valve 4. Pilot balloon 5. Inflating tube 6. Standard connector
Specifications	1. Cuffed Endotracheal tubes: 2.5mm-10.0mm; 2. Uncuffed Endotracheal tubes: 2.0mm-10.0mm	1. Cuffed Endotracheal tubes: 2.0mm-10.0mm; 2. Uncuffed Endotracheal tubes: 2.0mm-10.0mm
Materials	The products are primarily made from polyvinyl chloride (PVC) materials.	The disposable tracheal tubes are made from polyvinyl chloride material (PVC).
Mechanism of action	The Endotracheal tube intubation is the first aid basic operation of severe surgical and ICU departments. The basic principle is inserting the Endotracheal tube through the mouth, throat into the patient's trachea and to build artificial respiration channel to ensure patient breathes smoothly. The single use endotracheal tube has a smooth surface, and there is little mucosal injury for the trachea.	As the device functions in airway management/gas transport for anesthesia or resuscitation, it is required to be flexible and resistant to kinking. The airway management of patients is achieved by inserting the endotracheal tube into trachea through oral or nasal intubation.
Biocompatibility	The proposed device is considered as external communicating device in contact with tissue less than 30 days, and evaluation was conducted in accordance with #G95-1 and ISO 10993-1, which contains: 1. In Vitro Cytotoxicity 2. Skin Sensitization 3. Oral mucosa Irritation 4. Oral mucosa Prolonged Irritation 5. Genotoxicity Test 6. Implantation Test 7. Acute Systemic Toxicity Test	The device is considered as external communicating device in contact with tissue with cumulative contact up to 24 hours, and evaluation was conducted in accordance with #G95-1 and ISO 10993-1. The battery of testing included the following tests: 1. Cytotoxicity 2. Sensitization 3. Irritation

	8. Subchronic Systemic Toxicity Test 9. Endotoxin Test 10. Pyrogen 11. EO and ECH Residual Test 12. DEHP Residual Test	
Sterilization	Ethylene Oxide	Ethylene Oxide
Performance	The performance of the endotracheal tubes was evaluated in accordance with ISO 5361: 2012. The testing items contain: 1. Size designation; 2. Dimensions (including basic dimensions, inside diameter, outside diameter, tracheal tubes connectors, machine end, inside diameter of the machine end, patient end, opening at the patient end); 3. Tracheal tube bevel (including angle of bevel, free from sharp edges); 4. Tracheal tubes cuffs (including tube collapse, free of sharp edges); 6. Inflating system for cuffs (including outside diameter, angle between the inflating tube and at the tracheal tube at the point of separation, pilot balloon); 7. Curvature of the tube (including radius of curvature, maintain intended shape); 8. Kink resistance; 9. Additional requirement for Murphy eye; 10. Sterility assurance; 11. Marking. The results showed that the endotracheal tubes meet the	Essential performance of the shaft of the tube are evaluated according to the following standard respectively: -ISO 5361: 2012 The testing items contain: 1. Size designation; 2. Dimensions (including basic dimensions, inside diameter, outside diameter, tracheal tubes connectors, machine end, inside diameter of the machine end, patient end, opening at the patient end); 3. Tracheal tube bevel (including angle of bevel, free from sharp edges); 4. Tracheal tubes cuffs (including tube collapse, free of sharp edges); 6. Inflating system for cuffs (including outside diameter, angle between the inflating tube and at the tracheal tube at the point of separation, pilot balloon); 7. Curvature of the tube (including radius of curvature, maintain intended shape); 8. Kink resistance; 9. Additional requirement for Murphy eye; 10. Sterility assurance; 11. Marking. -ISO 11990-1: 2011

	requirement of ISO 5361.	The testing results demonstrate that the proposed devices meet the requirements of the standards listed above.

Table 2: Substantial equivalence comparison between Reinforced Endotracheal tube and BEVER™ Reinforced Endotracheal Tube.

Items	**The proposed device- Reinforced Endotracheal tube**	**The predicate device- BEVER™ Reinforced Endotracheal Tube K111406**
Classification	II 21 CFR 868.5730 BTR	II 21 CFR 868.5730 BTR
Indications for use	The Reinforced Endotracheal tube is intended for airway management by oral or nasal intubation of the trachea during anesthesia. It is a device inserted into the trachea through the mouth or nose to facilitate breathing and it may be used where the patient's neck is likely to be moved of flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.	The BEVER™ Reinforced Endotracheal Tube is indicated for airway management by oral or nasal intubation of the trachea during anesthesia. The product may be used where the patient's neck is likely to be moved or flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.
Structure and composition	The cuffed tube: 1. Main tube 2. Cuff 3. Inflating system (contains inflating tube, valve and pilot balloon) 4. Reinforced stainless steel The uncuffed tube: 1. Main tube 2. Reinforced stainless steel	The cuffed tube: 1. Main tube 2. Cuff 3. Inflating system (including inflating tube, valve and pilot balloon) 4. Steel reinforcement 5. Standard connector The uncuffed tube: 1. Main tube 2. Steel reinforcement 3. Standard connector
Specifications	Reinforced cuffed/uncuffed Endotracheal tubes: 3.0mm-	1. Cuffed BEVER™ Reinforced Endotracheal tubes:

	9.0mm	3.0mm-10.0mm; 2. Uncuffed BEVER™ Reinforced Endotracheal tubes: 2.0mm-7.0mm
Materials	The products are primarily made from polyvinyl chloride (PVC) materials, and the reinforced stainless steel is made by stainless steel.	Tube is made of PVC material and stainless steel wire.
Mechanism of action	The Reinforced Endotracheal tube intubation is the first aid basic operation of severe surgical and ICU departments. The basic principle is inserting the tube through the mouth, throat into the patient's trachea and to build artificial respiration channel to ensure patient breathes smoothly. The tube has a smooth surface, and there is little mucosal injury for the trachea. The additional metal wire spiral reinforcement to provide kink-resistance.	The BEVER™ Reinforced Endotracheal Tube is an Endotracheal tube with additional metal wire spiral reinforcement to provide kink-resistance. The product is typically used during operations where a high degree of flexibility is required from the tube, for instance prone position, head and neck surgery, and oral surgery, which is indicated for airway management by oral or nasal intubation of the trachea during anesthesia.
Biocompatibility	The proposed device is considered as external communicating device in contact with tissue less than 30 days, and evaluation was conducted in accordance with #G95-1 and ISO 10993-1, which contains: 1. In Vitro Cytotoxicity 2. Skin Sensitization 3. Oral mucosa Irritation 4. Oral mucosa Prolonged Irritation 5. Genotoxicity Test 6. Implantation Test 7. Acute Systemic Toxicity Test	Biocompatibility testing was performed based on ISO 10993 standards. The subject device passed the following biocompatibility testing: 1. Cytotoxicity 2. Sensitization 3. Irritation 4. Genotoxicity 5. Implantation

	8. Subchronic Systemic Toxicity Test 9. Endotoxin Test 10. Pyrogen 11. EO and ECH Residual Test 12. DEHP Residual Test	
Sterilization	Ethylene Oxide	Ethylene Oxide
Performance	The performance of the endotracheal tubes was evaluated in accordance with ISO 5361: 2012. The testing items contain: 1. Size designation; 2. Dimensions (including basic dimensions, inside diameter, outside diameter, tracheal tubes connectors, machine end, inside diameter of the machine end, patient end, opening at the patient end); 3. Tracheal tube bevel (including angle of bevel, free from sharp edges); 4. Tracheal tubes cuffs (including tube collapse, free of sharp edges); 6. Inflating system for cuffs (including outside diameter, angle between the inflating tube and at the tracheal tube at the point of separation, pilot balloon); 7. Curvature of the tube(including radius of curvature, maintain intended shape); 8. Kink resistance; 9. Additional requirement for Murphy eye (Size and location); 10. Sterility assurance; 11. Marking.	The dimension, design, material, sterility, packaging and labeling of BEVER™ Reinforced Endotracheal tubes are conformed with ISO 5361: 1999. The testing items contain: 1. Size designation; 2. Dimensions (including basic dimensions, inside diameter, outside diameter, tracheal tubes connectors, machine end, inside diameter of the machine end, patient end, opening at the patient end); 3. Tracheal tube bevel (including angle of bevel, free from sharp edges); 4. Tracheal tubes cuffs (including tube collapse, free of sharp edges); 6. Inflating tubes for cuffs (including outside diameter, angle between the inflating tube and at the tracheal tube at the point of separation, pilot balloon); 7. Curvature of the tube (including radius of curvature, maintain intended shape); 8. Kink resistance; 9. Additional requirement for Murphy eye (Size and location); 10. Sterility assurance; 11. Marking. The results showed that

	The results showed that the endotracheal tubes meet the requirement of ISO 5361.	BEVER™ Reinforced Endotracheal tubes are conformed to ISO 5361: 1999.

8. Non-Clinical Performance Data

8.1 Shelf life test

After accelerated aging, the package integrity and physical performance of the proposed devices were tested, and all of the results meet the acceptance criteria. Therefore, the product has a shelf life of 5 years was proved.

8.2 EO sterilization validation

The sterilization validation was conducted according to ISO 11135-1:2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. The sterilization validation, bioburden test, product sterility test, and Biological Indicators (BI) sterility test were conducted.

8.3 Biocompatibility test

The Endotracheal tubes have been subjected to biocompatibility studies to demonstrate the biocompatibility of the device. The biocompatibility studies were evaluated in accordance with #G95-1 and ISO 10993-1. There is no additional risk for the proposed products when compared with the predicate devices. The Biocompatibility testing show below:

In Vitro Cytotoxicity
Skin Sensitization
Oral mucosa Irritation
Oral mucosa Prolonged Irritation
Genotoxicity Test
Implantation Test
Acute Systemic Toxicity Test
Subchronic Systemic Toxicity Test
Endotoxin Test
Pyrogen
EO and ECH Residual Test
DEHP Residual Test

8.4 Performance test

The performance of the endotracheal tubes was evaluated in accordance with ISO 5361: 2012. The results showed that the endotracheal tubes meet the requirement of ISO 5361, which also demonstrated comparable results between the proposed devices and predicate devices.

9. Clinical Performance Data

As Endotracheal tubes have been on the global markets for many years already (including cuffed/uncuffed normal and reinforced endotracheal tubes), there is enough evidence to demonstrate substantial equivalence for the use of the device. Therefore, there was no clinical testing needed for supporting the device as the indications for use is equivalent to the predicate device. In the substantial equivalence of the device, the detail information of non-clinical testing would be supported.

10. Statement of Substantial Equivalence

The Indications for Use and technological characteristics for Endotracheal tubes and Reinforced Endotracheal tubes are same to the referenced predicate devices (K140228 and K111406). The non-clinical performance testing demonstrates that the proposed devices are as safe and as effective as the predicate devices. Therefore, the results show that it is Substantially Equivalent (SE) between products and predicate devices.