cuffDEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 7, 2017

Tianjin Medis Medical Device Co., Ltd.
% Mike Gu
Regulatory Affairs Manager
Osmunda Medical Device Consulting Co., Ltd
Level 7, Jin Gui Business Center, 982 Cunyun Road
Baiyun District
Guangzhou, 510420
CHINA

Re: K160694
Trade/Device Name: Disposable Endotracheal Tube, Sterile and Accu Cuff™
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR, BSK
Dated: March 8, 2017
Received: March 10, 2017

Dear Mike Gu:

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,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
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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)*
K160694

Device Name
Disposable Endotracheal tube, Sterile

Accu Cuff

Indications for Use *(Describe)*
The Sterile Disposable Endotracheal Tube device is intended for oral or nasal intubation and for airway management.

The Accu-Cuff device is intended to inflate cuffs and to monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.

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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510(k) Summary

Updated: April 07, 2017

In accordance with 21 CFR 807.87 the following summary of information is provided:

I. SUBMITTER

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II. DEVICE

Name of Device:	Disposable Endotracheal Tube, Sterile Accu Cuff™
Common/Usual Name:	Tracheal tube
Classification Panel:	Anesthesiology
Classification:	868.5730 (Tracheal tube)
Class:	II
Product Code:	BTR, BSK

III. PREDICATE DEVICES

Endotracheal Tubes

Well Lead Endotracheal Tube (K042683)

Well Lead Reinforced Endotracheal Tube(K073383)

TIGER ENDOTRACHEAL TUBES (VARIOUS MODELS AND SIZES)(K041311)

Inflatable Tracheal Tube Cuff

Cuff Pilot™ (K142103)

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The tracheal tube is disposable and supplied as sterile. It is available in a number of sizes/variants. The tracheal tube is primarily made of polyvinyl chloride. The device is used for airway management by connecting to oxygen delivery equipment via a connector. Reinforced ETTs may be used to reduce the potential for kinking whenever an unusual positioning of the head or neck is required following intubation. All variants have a radio-opaque line embedded into the tube which enables identification the device when the patient is X-rayed. All variants have a hole at the tip called a Murphy's eye and a standard connector.

Cuffed variants are composed of an inflatable cuff, a lumen and pilot balloon with a one-way valve or pressure indicator. The cuff is specified with high volume and standard volume which is intended to be inflated in the trachea in order to seal the device to prevent loss of gas bypassing the tube and the inhalation of vomit.

The patient end, the cuff and the tubular body of these tracheal tubes have short-term contact (< 30 days) with mucous membrane of upper airway.

Separately, Accu-cuff™ is used for pre-use check and monitoring the cuff pressure in intubation, treatment and extubation process. The user can Judge the change of intra-cuff pressure by observing the change of black line's location. When the black line point to the zone between the Minimum level of green zone and white line, it means the intra-cuff is too low and need to inflate to cuff. When the black line point to the zone between the Maximum level of green zone and red line, it means the intra-cuff is over-pressurizing and need to deflate.

V. INDICATION FOR USE

The Sterile Disposable Endotracheal Tube device is intended for oral or nasal intubation and for airway management.

The Accu-Cuff device is intended to inflate cuffs and to monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.

VI. SUBSTANTIAL EQUIVELENCE

Substantial equivalency is claimed against the following device:

Table 6.1 Substantial equivalency discussion

No.	Proposed Devices	Predicate Devices
1	Standard Endotracheal Tube, cuffed and uncuffed series	k042683
2	Endotracheal tube Reinforced, cuffed and uncuffed	k073383
3	Endotracheal tube Nasal Preformed, cuffed and uncuffed	k041311
4	Endotracheal tube Oral Preformed cuffed and uncuffed	
5	Accu Cuff™	k142103

Table 6.2 Equivalency discussion of Standard Endotracheal Tube, cuffed and uncuffed series

Specification	**Predicate Device**	**Proposed Device**	**Discussion of Differences**
Device name	Well Lead Endotracheal Tube	Disposable Endotracheal tube, sterile	
K number	**k042683**	—	
Intended use	The device is intended for oral or nasal intubation and for airway management.	The device is intended for oral or nasal intubation and for airway management.	Identical
Outer diameter	cuffed :3.3-13.3mm uncuffed :2.7-13.3mm	cuffed :3.3-13.3mm uncuffed :2.7-13.3mm	Identical
Tube length	cuffed :145-330mm uncuffed :140-330mm	cuffed :145-330mm uncuffed :140-330mm	Identical
Cuff inflated diameter	Standard cuff:12-27mm High volume cuff:12-27mm	Standard cuff:12-27mm High volume cuff:12-27mm	Identical
Cuff pressure (if applicable)	20 $cmH_20 \leqq P < 30$ cmH_20	20 $cmH_20 \leqq P \leqq 29$ cmH_20	Identical
Materials	Polyvinyl chloride, polypropylene	Polyvinyl chloride, polypropylene	Identical
Structure composition	Connector, inflating tube, Check valve (include Pilot balloon), Airway Tube, Cuff (if available).	Connector, Inflation tube, pilot balloon and valve (cuffed), Airway Tube, Cuff (if available), Accu Cuff™ (if available)	Similar. The proposed device has an extra Accu Cuff™ component, refer to table 6.5.
Anatomical Sites	The tubular body and the cuff have limited or prolonged contact with mucous membrane of oral/nasal cavity and the tracheal.	The tubular body and the cuff have limited or prolonged contact with mucous membrane of oral/nasal cavity and the tracheal.	Identical
Contact duration	Less than 30 days	Less than 30 days	Identical
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Identical
Shelf life	5 years	5 years	Identical
Packing	PE / PET composite film and dialysis paper	PE / PET composite film and dialysis paper	Identical
Sterilization	EO	EO	Identical

Table 6.3 Equivalency discussion of Endotracheal tube Reinforced, cuffed and uncuffed series

Specification	Predicate Device	Proposed Device	Discussion of Differences
Device name	Well Lead Reinforced Endotracheal Tube	Disposable Endotracheal tube, sterile	/
K number	K 073383	——	/
Intended use	The Well Lead Reinforced Endotracheal Tubes are designed for oral or nasal intubation for airway management during anaesthesia. 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.	The device is intended for oral or nasal intubation and for airway management.	Similar. Two devices are both used for airway management
Size	Cuffed: in 0.5mm ID increments from size 5.0 to 9.5 inclusive, totaling 10 sizes. uncuffed: in 0.5mm ID increments from size 3.0 to 9.5 inclusive, totaling 14 sizes.	Cuffed: in 0.5mm ID increments from size 5.0 to 9.0 inclusive, totaling 10 sizes. uncuffed: in 0.5mm ID increments from size 3.0 to 9.5 inclusive, totaling 14 sizes.	Similar. The size of proposed device meets the requirement of section 5 of ISO 5361.
Outer diameter	Cuffed:7.0-13.0mm Uncuffed: 4.3-13.0mm	Cuffed:7.0-13.0mm Uncuffed: 4.3-13.0mm	Identical
Tube length	Cuffed:245-330mm Uncuffed: 165-330mm	Cuffed:245-330mm Uncuffed: 165-330mm	Similar. The size of proposed device meets the requirement of section 5 of ISO 5361.
Cuff inflated diameter	Cuffed:17-27mm High volume cuff:12-27mm	Cuffed:17-27mm High volume cuff:12-27mm	Identical
Cuff pressure (if applicable)	20 $cmH_20 \leqq P < 30$ cmH_20	20 $cmH_20 \leqq P \leqq 29$ cmH_20	Identical

Specification	Predicate Device	Proposed Device	Discussion of Differences
Materials	Polyvinyl chloride, polypropylene	Polyvinyl chloride, polypropylene	Identical
Structure composition	Connector, Inflating tube, Check valve (include pilot balloon), reinforced metal, Cuff (if available).	Connector, Inflation tube, pilot balloon and valve (cuffed), Airway Tube, reinforced metal , Cuff (if available), Accu Cuff™ (if available)	Similar. The proposed device has an extra Accu Cuff™ component, refer to table 6.5.
Anatomical Sites	The tubular body and the cuff have limited or prolonged contact with mucous membrane of oral/nasal cavity and the tracheal.	The tubular body and the cuff have limited or prolonged contact with mucous membrane of oral/nasal cavity and the tracheal.	Identical
Contact duration	Less than 30 days	Less than 30 days	Identical
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Identical
Shelf life	5 years	5 years	Identical
Packing	PE / PET composite film and dialysis paper	PE / PET composite film and dialysis paper	Identical
Sterilization	EO	EO	Identical

Table 6.4 Equivalency discussion of Endotracheal tube Nasal and Oral Preformed cuffed and uncuffed series

Specification	Predicate Device	Proposed Device	Discussion of Differences
Device name	TIGER ENDOTRACHEAL TUBES (VARIOUS MODELS AND SIZES)	Disposable Endotracheal tube, sterile	/
K number	**K041311**	——	/

Specification	Predicate Device	Proposed Device	Discussion of Differences
Intended use	The intended use for all the product variants is grouped into different sections: CATEGORY 2 (uncuffed. nasal only) and CATEGORY 5 (cuffed, nasal only): The intended use of this device is to be intubated into a patient's trachea via the nose for airway management, specifically for use in surgical procedures involving the head, neck and face. CATEGORY 3 (uncuffed, oral only) and CATEGORY 6 (cuffed, oral only): The intended use of this device is to be intubated into a patient's trachea via the mouth for airway management, specifically for use in surgical procedures involving the head, neck and face.	The device is intended for oral or nasal intubation and for airway management.	Similar. Two devices are both used for airway management
Size	Uncuffed (nasal only and oral only): provide in 0.5mm ID increments from sizes 2.0 to 10.0 inclusive, totaling 17Sizes. Cuffed (nasal only and oral only): provide in 0.5mm ID increments from sizes 4.0 to 10.0 inclusive, totaling 13 sizes.	Nasal only (cuffed and uncuffed): provide in 0.5mm ID increments from sizes 3.0 to 10.0 inclusive, totaling 15 Sizes. Oral only (cuffed and uncuffed): provide in 0.5mm ID increments from sizes 3.0 to 10.0 inclusive, totaling 15 Sizes.	Identical. The size of proposed device meets the requirement of section 5 of ISO 5361.
Outer diameter	Not provided	Oral Preformed:4.0-13.3mm Nasal Preformed: 4.0-13.3mm	Similar with the predicate devices in table 12.2.

Specification	Predicate Device	Proposed Device	Discussion of Differences
Tube length	Not provided	Oral Preformed:165-330mm Nasal Preformed:290-400mm	The tube length of proposed device meets the requirement of section 5 of ISO 5361.
Cuff inflated diameter	Not provided	Standard cuff:12-27mm High volume cuff:12-27mm	/
Cuff pressure (if applicable)	20 $cmH_20 \leqq P < 30$ cmH_20	20 $cmH_20 \leqq P \leqq 29$ cmH_20	Identical
Materials	Polyvinyl chloride, polypropylene	Polyvinyl chloride, polypropylene	Identical
Structure composition	Connector, inflating tube, Check valve (include Pilot balloon), Airway Tube, Cuff (if available).	Connector, Inflation tube, pilot balloon and valve (cuffed), Airway Tube, Cuff (if available), Accu Cuff™ (if available)	Similar. The proposed device has an extra Accu Cuff™ component, refer to table 6.5.
Anatomical Sites	The tubular body and the cuff have limited or prolonged contact with mucous membrane of oral/nasal cavity and the tracheal.	The tubular body and the cuff have limited or prolonged contact with mucous membrane of oral/nasal cavity and the tracheal.	Identical
Contact duration	Less than 30 days	Less than 30 days	Identical
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Identical
Shelf life	5 years	5 years	Identical
Packing	PE / PET composite film and dialysis paper	PE / PET composite film and 70g dialysis paper	Identical
Sterilization	EO	EO	Identical

Table 6.5 Equivalent discussion of pressure indicator (Accu Cuff™)

Attribute	Predicate Device Cuff Pilot™ (K142103)	Proposed Device Accu Cuff™	Discussion of Differences
Indications for Use	To monitor intra-cuff pressures of supraglottic airways.	To inflate cuffs and to monitor intra-cuff pressures of endotracheal, supraglottic airways, or tracheostomy tubes.	Similar. Two devices are both used to indicate the intra-cuff pressure of artificial airway tube.
Environment of use	To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may have an artificial airway. It may also be used in MRI suites when attached to airways that are MR conditional or MR Safe.	To be used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated. The metal-contained models are MR unsafe.	The metal-contained models of proposed device are MR unsafe, and be marked with MR unsafe in labels.
Patient population	Patients who have an artificial airway and for which the user would like to monitor cuff pressure, pediatric to adult.		Identical
Working principle	Use the pressure difference between the pressure indicator cavity and the atmospheric pressure, the elastic piece will be concaved and then drive the black line on the joint lever move and indicate the intra-cuff pressure.		Identical
Technology	Bellows that move with changes in pressure Contracts with higher pressures Expands with lower pressures	Diaphragm/bellows that move with changes in pressure Expands with higher pressures Rebounds with lower pressures	Mechanisms are same.
Indication method	The Bottom cover have Color mark, when the black line move to the white line ,which means the intra –cuff pressure is decreased, move to the red line show the intra-cuff pressure is increased. When the black line site in the Green zone, the intra-cuff pressure is safe.	The Outer Cylinder have Color mark, the yellow zone, green zone and red zone. When the black line in the yellow zone means the pressure is too low, the red zone indicate the intra cuff pressure is too large, that need to deflate. The black line in the green zone which means the intra cuff pressure is safe.	The mechanism is identical, only differ in color of indication line.
Method of inflating cuff	Use an independent syringe (normal practice). Manual		Identical
Component	Outer Cylinder, Valve, plate, Bellows, Black line, Bottom cover,	Top cover, PP cap, Cross, Gasket, Silicone tube, Bottom	Similar. The components of proposed device can

	Color mark, Luer connector, connector	cover of check valve, Sealing cover, Supported ring ,Elastic piece, Bottom cover, Silicone ring(black line), Join lever , Color mark	perform the designed functions, refer to Appendix Q4.
Material	Outer Cylinder, plate, Bottom cover: Polycarbonate Bellows, Valve : Silicone Rubber	Top cover, Bottom cover, Supported ring, Join lever, Bottom cover of check valve: Polycarbonate. Sealing cover, Silicone tube, Gasket, Silicone ring(black line), Elastic piece: Silicone Rubber PP cap: Polypropylene Cross: ABS (Acrylonitrile Butadiene Styrene)	Similar. The materials of the proposed device are safe in biocompatibility, refer to Appendix P.
Attaches to the Cuff Inflation Pilot	Yes, via a luer fitting may be permanently attached to an airway's cuff inflation line	Yes, via a luer fitting may be permanently attached to an airway's cuff inflation line	Identical
Types of airways to which it can be used	Supraglottic airway	Endotracheal tube	Similar. The proposed component is a pressure monitoring device, refer to Appendix Q4.
Single patient, disposable	Yes	Yes	Identical
Pressure Range of the device	0 to 80 cm H_2O	0-40 cm H_2O	Similar. The proposed device is used under range 20-29 cmH_2O which is under 40 cmH_2O.
Detection of "good range"	Color coded zones	Color coded zones	Identical
Sterilization	Non-sterile and sterile	Sterile	Identical
Working pressure range	+/- 5 cmH_2O up to 80 cmH_2O	+ 4 cmH_2O at 20 cmH_2O - 4 cmH_2O at29 cmH_2O	The tolernace of pressure is similar. Refer to Appendix S and T for clinical evidence of range 20 cmH_2O-29 cmH_2O.
Shelf-life	3 years	5 years	Similar. Refer to Appendix O for shelf life validation.

VII. PERFORMANCE DATA

The disposable tracheal tube has been evaluated by biocompatibility testing, device performance, sterilization and shelf life validation and EO/ECH residue analysis.

The performance tests were conducted with the following standards.

- ISO 10993-1:2009/(R) 2013, Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process;
- ISO 10993-3:2014 Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5 :2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-6:2007 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization;
- ISO 5361:2012 Anaesthetic and respiratory equipment -- Tracheal tubes and connectors; including dimensional; leakage; kinking; and radiopacity testing.
- ASTM F88/F88M-09, Standard Test Method For Seal Strength Of Flexible Barrier Materials
- ASTM F640-2012 Standard Test Methods for Determining Radiopacity for Medical Use

VIII. CONCLUSION

Tianjin Medis Medical Device Co., Ltd. considers the Disposable Endotracheal tube, Sterile and the Accu Cuff™ to be as safe, as effective, and performance is substantially equivalent to the predicate devices.