July 30, 2019

Tianjin Medis Medical Device Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K190274
Trade/Device Name: Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: June 26, 2019
Received: July 3, 2019

Dear Diana Hong:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190274

Device Name
Endotracheal Tube

Indications for Use *(Describe)*
The device is intended for airway management by oral intubation and aid in the removal of subglottic secretions.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Exhibit #8 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K190274

1. Date of Preparation: 07/12/2019

2. Sponsor Identification

Tianjin Medis Medical Device Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Endotracheal Tube
Common Name: Tracheal Tube

Regulatory Information
Classification Name: Tracheal Tube;
Classification: II;
Product Code: BTR
Regulation Number: 21 CFR 868.5730;
Review Panel: Anesthesiology;

Intended Use Statement:

The device is intended for airway management by oral intubation and aid in the removal of subglottic secretions.

Device Description:

The proposed device, Endotracheal Tube is indicated for airway management and aid in the removal of subglottic secretions. The proposed device is available in ETT-X32 and ETT-X22 two types, the difference between these two types is that the ETT-X32 is provided with pressure indicator which is used to monitor intra-cuff pressure. Both two types are available in a series sizes from 6.0mm~9.0mm in an increment of 0.5mm. The proposed device is intended for adult, provided in sterile and single use.

5. Identification of Predicate Devices

Predicate Device 1
510 (k) Number: K141939
Product Name: TELEFLEX ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port

Predicate Device 2
510 (k) Number: K160694
Product Name: Disposable Endotracheal Tube, Sterile

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test provided in this submission include:

Physical, Mechanical and Chemical Tests performed on the proposed device include

Dimension	Clause 5.2 of ISO 5361:2016
Material	Clause 5.3 of ISO 5361:2016
Tracheal tube bevel	Clause 5.4 of ISO 5361:2016
Tracheal tube cuffs	Clause 5.5 of ISO 5361:2016
Inflating system for cuffs	Clause 5.6 of ISO 5361:2016
Curvature of the tube	Clause 5.7 of ISO 5361:2016
Radiopaque marker	Clause 5.8 of ISO 5361:2016
Kink resistance	Clause 5.9 of ISO 5361:2016
Conical connectors	Clause 5.1 of ISO 5356-1:2004
Gauging	Clause 4.1 of ISO 594-1:1986
Liquid leakage	Clause 4.2 of ISO 594-1:1986
Air leakage	Clause 4.3 of ISO 594-1:1986
Separation force	Clause 4.4 of ISO 594-1:1986
Stress cracking	Clause 4.5 of ISO 594-1:1986

Sterile Barrier Packaging Testing performed on the proposed device include

Seal strength	ASTM F88/F88-15
Dye penetration	ASTM F1929-15

Sterilization and Shelf Life Testing performed on the proposed device include

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical and Package Tests were performed on accelerated aging samples to verify the claimed shelf life of the device

Biocompatibility Testing:

The patient-contact materials of the proposed device are identified and biocompatibility testing is performed according to ISO 10993 standards. The test items include Cytotoxicity, Sensitization, Intracutaneous, Systemic Toxicity, Subchronic Systemic Toxicity, Bacterial Reverse Mutation, Gene Mutation, Implantation and Pyrogen.

Simulated Transportation Testing

Simulated transportation test is performed per ASTM D 4169 on the final product and the test result can demonstrate the device package can maintain its integrity during transportation.

Bond strength test

All joints for the proposed device are tested for its bond strength and the test result can meet acceptance criteria.

Air flow resistance test
Air flow resistance rest are conducted on the proposed device and equivalent device and the test result have no significant difference between proposed device and equivalent device.

The test results demonstrated that the proposed device complies with the following standards:

- ISO 5361:2016 Anaesthetic and Respiratory Equipment-Tracheal Tubes and Connectors
- ISO 594-1:1986 Conical Fittings With a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment-Part 1: General Requirements
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- 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 10993-6:2016 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 10993-11:2017 Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals
- USP 41-NF36:2017 <151> Pyrogen Test

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics for ETT-X22

Item	Proposed Device	Predicate Device 1 K141939	Remark
Classification	II	II	SE
Product Code	BTR	BTR	SE
Regulation Number	21CFR 868.5730	21 CFR 868.5730	SE
Intended Use	The device is intended for airway management by oral intubation and aid in the removal of subglottic secretions.	The Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is indicated for airway management by oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of subglottic secretions	SE
Configuration	Connector Inflating Tube Check Valve (with pilot balloon) Airway Tube Cuff Suction Tube Suction Connector Suction Cap	Connector Main Tube Inflation line Pilot balloon Bi-directional Valve Cuff Balloon Suction lumen Connector	Discussion 1
Materials	Polypropylene; Polyvinyl chloride; Acrylonitrile butadiene styrene; Silicone gel	Polyvinyl chloride;	Discussion 2
Size (mm)	6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm	6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm	SE
Intended population	Adult	Adult	SE
Anatomical Site	Oral	Oral	SE
Single Use	Single Use	Single Use	SE
Cuff inflamed diameter	20~27mm	Unknown	Discussion 3
Tube length	285~330mm	Unknown	
Ink marks	Yes	Yes	SE
Radiopaque markers	Yes	Yes	SE
Murphy's eye	Yes	Yes	SE
Beveled tip	Yes	Yes	SE
Patient contact duration	Less than 30 days	Less than 30 days	SE
Packing material	60g French paper and polythylene terephthalate	10 individually packaged in either banana pack or Tyvek pouches per dispenser box	Discussion 4

Shelf-life	5 years	12 months (extending to 60 months as data becomes available)	
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	SE
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993 standards requirements	SE
Intracutaneous Irritation	No Irritation		
Skin Sensitization	No Sensitization		
Acute Toxicity	No Systemic Toxicity		
Subchronic Toxicity	No Subchronic Toxicity		
Bacterial Reverse Mutation	Not induce backward mutation		
Gene Mutation Test	Non-mutagenic		
Implantation	Non-irritant to the subcutaneous tissue		
Pyrogen Test	No pyrogen		
Method	Ethylene Oxide	Ethylene Oxide	SE
SAL	10^{-6}	10^{-6}	SE

Discussion 1

The components airway tube and suction tube are not listed by predicate device, however, these two tubes are included in the main tube of predicate device and the function for these two components are same as predicate device. Therefore, the difference in components does not raise difference questions of safety or effectiveness.

Discussion 2

The material of proposed device is different from predicate device. However, the biocompatibility tests have been conducted on the proposed device and the test result can meet the requirements of ISO 10993 series standards. Therefore, this difference does not raise difference questions of safety or effectiveness between proposed device and predicate device.

Discussion 3

The cuff inflamed diameter and tube length for predicate device is unknown and the substantially equivalence between proposed device and equivalent device cannot be determined. However, the performance test has been conducted on the proposed device and the test result comply with related standards requirements. Therefore, this difference does not raise difference questions of safety or effectiveness between proposed device and predicate device.

Discussion 4

The packing materials and shelf life for proposed device are different from predicate device. The function of package is used to protected device from damaging during transportation, store. The simulated transportation test and package integrity test has been conducted on the proposed device, the results can demonstrate that the package is still integrity and there is no damage for device. In addition, the package integrity and device performance after accelerated aging can demonstrate that the package of the proposed device can maintain the sterility of the product during its claimed shelf life and the performance test result can meet the requirements of related standards. Therefore, this difference does not raise difference questions of safety or effectiveness between proposed device and predicate device.

Table 2 Comparison of Technology Characteristics for ETT-X32

Item	Proposed Device	Predicate Device 1 K141939	Predicate Device 2 K160694	Remark
Classification	II	II	II	SE
Product Code	BTR	BTR	BTR	SE
Regulation Number	21CFR 868.5730	21 CFR 868.5730	21 CFR 868.5730	SE
Intended Use	The device is intended for airway management by oral intubation and aid in the removal of subglottic secretions.	The Teleflex ISIS™ HVT™ Tracheal Tube, Cuffed with Subglottic Secretion Suction Port is indicated for airway management by oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of subglottic secretions	The sterile Disposable Endotracheal Tube is intended for oral or nasal intubation and for airway management.	SE
Configuration	Connector Inflating Tube Airway Tube Cuff Suction Tube Suction Connector Suction Cap Pressure Indicator	Connector Main Tube Inflation line Pilot balloon Bi-directional Valve Cuff Balloon Suction lumen Connector	Connector Inflation tube Pilot balloon Check Valve Airway tube Cuff Accu Cuff™	Discussion 1
Size (mm)	6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm	6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm	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.	Discussion 2

Intended population	Adult	Adult	Adult	SE
Anatomical Site	Oral	Oral	Oral or Nasal	Discussion 3
Single Use	Single Use	Single Use	Single Use	SE
Pressure range	20cm H_2O≤P≤29cm H_2O	Not provided with pressure indicator	20cm H_2O≤P≤29cm H_2O	Discussion 4
Pressure measurement accuracy	+4cm H_2O at 20cm H_2O -4 cm H_2O at 29cm H_2O	Not provided with pressure indicator	+4cm H_2O at 20cm H_2O -4 cm H_2O at 29cm H_2O	
Cuff inflamed diameter	20~27mm	Unknown	12~27mm	Discussion 5
Tube length	285~330mm	Unknown	Oral tube:165~330mm Nasal tube: 290~400mm	
Ink marks	Yes	Yes	Yes	SE
Radiopaque markers	Yes	Yes	Yes	SE
Murphy's eye	Yes	Yes	Yes	SE
Beveled tip	Yes	Yes	Yes	SE
Patient contact duration	Less than 30 days	Less than 30 days	Less than 30 days	SE
Packing material	60g French paper and polythylene terephthalate	10 individually packaged in either banana pack or Tyvek pouches per dispenser box.	PE/PET composite film and dialysis paper.	Discussion 6
Shelf-life	5 years	12 months (extending to 60 months as data becomes available)	5 years	
Material	Polypropylene; Polyvinyl chloride; Acrylonitrile butadiene styrene; Silicone gel	Polyvinyl chloride;	Polyvinyl chloride; Polypropylene	Discussion 7
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	SE
Biocompatibility				
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993 standards requirements	Comply with ISO 10993 standards requirements	SE
Intracutaneous Irritation	No Irritation			

Skin Sensitization	No Sensitization			
Acute Toxicity	No Systemic Toxicity			
Subchronic Toxicity	No Subchronic Toxicity			
Bacterial Reverse Mutation	Not induce backward mutation			
Gene Mutation Test	Non-mutagenic			
Implantation	Non-irritant to the subcutaneous tissue			
Pyrogen Test	No pyrogen			
Sterilization				
Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	SE
SAL	10^{-6}	10^{-6}	10^{-6}	SE

Discussion 1

The components airway tube and suction tube are not listed by predicate device K141939, however, these two tubes are included in the main tube of predicate device and the function for these two components are same as predicate device K141939, additionally, the pressure indicator is not included in predicate device K141939, while this component is same as the Accu CuffTM included by predicate device K160694. Therefore, the difference in components does not raise difference questions of safety or effectiveness.

Discussion 2

The sizes for proposed device is same as predicate device K141939 and is different from predicate devices K160694. However, the sizes for proposed device are covered by the predicate device K160694. Therefore, the difference in the sizes does not raise difference questions of safety or effectiveness

Discussion 3

The intended anatomical site of proposed device is different from predicate device K160694. However, the oral intubation is also included by this predicate device. Therefore, the difference in components does not raise difference questions of safety or effectiveness

Discussion 4

The predicate device K141939 does not contain the component of pressure indicator, thus, there is no pressure range and pressure accuracy requirement for this device. The pressure indicator contained in proposed device is same as the predicate device K160694, therefore, the pressure range for proposed device is

identical to predicate device K160694 which can demonstrate the substantially equivalence between proposed device and predicate device.

Discussion 5

The cuff inflamed diameter and tube length for predicate device K141939 is unknown and the substantially equivalence between proposed device and equivalent device K141939 cannot be determined. However, the performance test has been conducted on the proposed device and the test result comply with related standards requirements. Besides, although the cuff inflamed diameter and tube length for proposed device is different from predicate device K160694, the diameter and length can be covered by predicate device K160694. Therefore, this difference does not raise difference questions of safety or effectiveness between proposed device and predicate device.

Discussion 6

The packing materials and shelf life for proposed device are different from predicate device. The function of package is used to protected device from damaging during transportation, store. The simulated transportation test and package integrity test has been conducted on the proposed device, the results can demonstrate that the package is still integrity and there is no damage for device. In addition, the package integrity and device performance after accelerated aging can demonstrate that the package of the proposed device can maintain the sterility of the product during its claimed shelf life and the performance test result can meet the requirements of related standards. Therefore, this difference does not raise difference questions of safety or effectiveness between proposed device and predicate device.

Discussion 7

The material of proposed device is different from predicate device. However, the biocompatibility tests have been conducted on the proposed device and the test result can meet the requirements of ISO 10993 series standards. Therefore, this difference does not raise difference questions of safety or effectiveness between proposed device and predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above and the nonclinical tests conducted, the proposed devices are determined to be as safe, as effective, and performs as well as the predicate devices.