July 21, 2022

Well Lead Medical Co., LTD.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K211543
Trade/Device Name: Wei Nasal Jet Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: June 20, 2022
Received: June 22, 2022

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 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)*
K211543

Device Name
Wei Nasal Jet Tube

Indications for Use *(Describe)*
WEI nasal jet tube is indication for airway management, inserted through nasal cavity. During and after insertion, the Jet Tube can supply jet ventilation intermittently. When the Jet tube is not in use, the main tube serves as the main oxygen supply channel, and oxygen is supplied through main tube. The PetCO2 Monitor tube can connect to CO2 monitoring machine to monitor CO2 status.

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

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

The assigned 510(k) Number: K211543

1. Date of Preparation: 06/20/2022

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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4. Identification of Proposed Device

Trade Name: Wei Nasal Jet Tube
Common Name: Nasopharyngeal airway

Regulatory Information

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

Indication for Use:
WEI nasal jet tube is indication for airway management, inserted through nasal cavity. During and after insertion, the Jet Tube can supply jet ventilation intermittently. When the Jet tube is not in use, the main tube serves as the main oxygen supply channel, and oxygen is supplied through main tube. The $PetCO_2$ Monitor tube can connect to CO_2 monitoring machine to monitor CO_2 status.

Device Description:
Wei Nasal Jet Tube is a sterile, single-use nasopharyngeal airway for airway management, monitor $PetCO_2$ and mechanical ventilation. Wei Nasal Jet Tube inserted into a patient's pharynx through the nose, it provides active, pulsatile and powerful supraglottic jet oxygenation and ventilation (SJOV) via a jet channel built into the wall of its distal end. It can be used to monitor $PetCO_2$ via another channel built into the wall and open to the middle lumen of the tube. Wei Nasal Jet Tube can also augment oxygen supplies for patients with respiratory suppression or apnea during difficult airway managements.

5. Identification of Predicate Device

510 (k) Number: K040657
Product Name: Boussignac/ Vygon Endotracheal Tribe

6. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K040657	Remark
Regulation No.	21 CFR 868.5730	21 CFR 868.5730	Same
Product Code	BTR	BTR	Same
Class	II	II	Same
Indication for Use	WEI nasal jet tube is indication for airway management, inserted through nasal cavity. During and after insertion, the Jet Tube can supply jet ventilation intermittently. When the Jet tube is not in use, the main tube serves as the main oxygen supply channel, and oxygen is supplied through main tube. The PetCO_2 Monitor tube can connect to CO_2 monitoring machine to monitor CO_2 status.	The Bousxignac/iygon Endotracheal Tube is indicated for airway management. The insufflation canals permit the delivery of intermittent jet ventilation and the administration of oxygen during tracheobronchial suctioning procedures. They also provide a supplemental means for administering oxygen during bronchoscopies. In these ventilatory modes, the main lumen serves as a channel for the elimination of expired gases. When the insufflation port is capped, the Boussignac/Vygon Endotracheal Tube can function as a standard tracheal tube with ventilation occurring through the main lumen. The Boussignac/iygon Endotracheal Tube is intended for oral/nasal intubation. The monitoring/irrigation lumens may be used for monitoring airway pressure, for irrigation of a patient's tracheobronchial tree, to aid in the removal of accumulated secretions, for sampling tracheal gases, for anesthetizing the trachea, or for introducing suitable medication in accordance with standard medical practices.	Similar
Configuration	Connector Main Tube	Connector 15mm Connector for Main Lumen	Similar

	$PetCO_2$ Monitor Tube Luer Cap of $PetCO_2$ Monitor Tube Cap of Jet Tube Connect Jet Tube 15 mm Connector	Insufflation Access Connecting Tube for Monitoring/Irrigation Lumen Pilot Balloon Valve for Cuff Inflation Cuff Beveled Tip	
Size (mm)	I.D. 5.0, 6.0, 7.0 mm	Adult, Cuffed: I.D. 7.0, 7.5, 8.0 mm Pediatric, Uncuffed: I.D. 2.5, 3.0, 3.5 mm.	Different
Intended population	Adult	Adult, Pediatric	Different
Anatomical Site	Nasal	Oral/Nasal	Different
Single Use	Single Use	Single Use	Same
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Patient Contact Material			
Main Tube	PVC and green pigment	Unknown	Different
PetCO2 Monitor Tube	PVC		
Luer Connector	PC		
Jet Tube	PVC and blue pigment		
15mm Connector	PP		
Biocompatibility			
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993 standards requirements	Same
Intracutaneous Irritation	No Irritation		
Skin Sensitization	No Sensitization		
Acute Toxicity	No Systemic Toxicity		
Subacute Toxicity	No Subacute Toxicity		
Bacterial Reverse Mutation	Not induce backward mutation		
Gene	Non-mutagenic		

Mutation Test			
Implantation	Non-irritant to the subcutaneous tissue		
Pyrogen Test	No pyrogen		
Sterilization			
Method	Ethylene Oxide	Ethylene Oxide	Same
SAL	10^{-6}	10^{-6}	Same

Similar Analysis 1- Indication for Use

The description of indication for use for proposed device is different from predicate device. However, both of them are indicated for airway management, jet ventilation and the administration of oxygen. Therefore, this difference does not affect substantially equivalence.

Similar Analysis 2- Configuration

The components were named by manufacturer and may be different from each other. From above table, the components for the proposed device are different from predicate device. The proposed device does not have the configuration of Insufflation Access Pilot Balloon Valve for Cuff Inflation and cuff. This difference was caused by that the proposed device is uncuffed. However, this difference does not affect intended use. Therefore, the difference in components does not affect substantially equivalence.

Different Analysis 3-Size

From above table, the size specifications for the proposed device is less than the predicate device. This difference was caused by different intended population. However, the sizes of proposed device are covered by the predicate device. Therefore, the difference in the sizes does not affect substantially equivalence.

Different Analysis 4- Intended Population

The intended population of proposed device is not same as the predicate device. However, the intended population for the proposed device can be covered by the predicate device. Therefore, the difference in the intended population does not affect substantially equivalence.

Different Analysis 5- Anatomical Site

The anatomical site of proposed device is oral, and this anatomical site can be covered by the predicate device. Therefore, the difference in the anatomical site does not affect substantially equivalence.

Different Analysis 6- Patient-contact Material

The patient-contact material for predicate device is unknown. 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 affect substantially equivalence between proposed device and predicate device.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISTA 2A, Transport test of single package product
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- 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 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity
- 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 10993-6: 2016 Biological Evaluation of Medical Devices-Part 6: Test for Local effects after implantation
- ISO 10993-3:2014 Biological Evaluation of Medical Devices-Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals
- USP <151> Pyrogen Test
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 5356-1: 2015 Anaesthetic and Respiratory Equipment - Conical Connectors - Part 1: Cones and Sockets
- ASTM F1573-95 (2000) Standard Specification for Anesthetic Equipment—Oropharyngeal and Nasopharyngeal Airways
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 10993-17:2002 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances

Connecter testing listed in following table were performed on the proposed device. The test results show that the device conform to the requirements of related standards.

Table 2 Performance Testing

Test	Standard
Conical connectors	ISO 5356-1:2015: Anaesthetic and respirator equipment-Conical connectors-Part 1: Cones and sockets
Luer connector	ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods

The comparative test for length, diameter, bevel angle, curvature, kink resistance and connectors were performed on the proposed device and predicate device. A summary of the tests performed is provided in the table below:

Table 3 Summary of Performance Testing

Test	Test Method Summary	Result and Conclusion
Length Test	Verify length using specified measurement tools. Record measurements.	Length verification met acceptance criteria. The difference between the proposed device and the predicate device does not affect the safety and effectiveness of the product.
Outer Diameter Test	Verify dimensions using specified measurement tools.	The test results comply with the requirements of acceptance criteria of the proposed device the test result of the proposed device and the predicate device are very similar.
Radius of Curvature Test	The curvature radius of the product is measured using a curvature test plate.	Curvature radius met acceptance criteria. The difference between the proposed device and the predicate device does not affect the safety and effectiveness of the product.
Angle of Bevel Test	The curvature radius of the product is measured using angle ruler.	The test results comply with the requirements of acceptance criteria of the proposed device and the test result of the proposed device and the predicate device are similar.
Inner Diameter Test	Verify dimensions using plug gauge.	Both test result of the proposed device and the predicate device comply with the requirements of acceptance criteria of the proposed device
Kink Resistance Test	The proposed device was evaluated per ASTM F1573 to demonstrate that the device kink resistance.	Both test result of the proposed device and the predicate device comply with the requirements of acceptance criteria of the proposed device.

Connector Strength	Use a tensile test machine to apply a tensile load to the sample and determine whether the maximum tensile force meets the acceptance criteria.	Use a tensile test machine to apply a tensile load to the sample and determine whether the maximum tensile force meets the acceptance criteria.

Biocompatibility testing

The contact level of the proposed device is tissue, and the contact duration is prolonged contact (>24 hours to 30 days). The proposed device was evaluated for the following tests. The results for the biocompatibility testing showed that the proposed device is biocompatible.

- Cytotoxicity,
- Sensitization,
- Irritation,
- Systemic toxicity,
- Pyrogen,
- Subcutaneous Implant
- Subacute Toxic Implantation
- Bacterial Reverse Mutation
- Gene Mutation
- Particulate Matter
- Volatile Organic Compounds
- Toxicological Risk Assessment

Sterility, Shipping, and Shelf -life

The proposed device sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels were below the level of 20 EU/device in accordance with USP <85>. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 5 year shelf-life.

- Package integrity test – after environmental conditioning, simulated transportation testing in accordance to ISTA 2A on final, packaged, and sterile device.
- Sterile Barrier Packaging performed on the proposed device:
  - Visual inspection ASTM F1886/F1886M-16
  - Seal strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15
- Shelf-life of 5-years is validated using FDA recognized standard ASTM F1980 -16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

The subject device has the same intended use as the predicate device. The technological differences do not raise new questions of safety and effectiveness. The biocompatibility, sterility and bench performance testing demonstrate that the Wei Nasal Jet Tube is substantially equivalent to the predicate device.