December 23, 2019

Well Lead Medical Co., Ltd.
Jenny Zhu
Regulatory Affairs Specialist
No.47, Guomao Avenue South, Hualong, Panyu
Guangzhou, CN 511434 Guangdong

Re: K182739
Trade/Device Name: Endotracheal Tube with Evacuation Lumen
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal tube
Regulatory Class: Class II
Product Code: BTR
Dated: September 25, 2018
Received: September 28, 2018

Dear Jenny Zhu:

This letter corrects our substantially equivalent letter of December 11, 2019.

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,

Ka N. To -S5
2019.12.23 14:30:38 -05'00'

For 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)*

K182739

Device Name

Endotracheal Tube with Evacuation Lumen

Indications for Use *(Describe)*

The Endotracheal Tube with Evacuation Lumen is intended for oral intubation and drainage of the subglottic space for airway management.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	12/23/2019
Submitter:	WELL LEAD MEDICAL CO., LTD. Address: C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Contact Person:	Jenny Zhu Regulatory Affairs Specialist WELL LEAD MEDICAL CO., LTD. Email: jenny_zhu@welllead.com.cn Tel: +86-20-84758878 Fax:+86-20-84758224
Device Name:	Endotracheal Tube with Evacuation Lumen
Common Name:	Tracheal Tube
Regulation Number:	21 CFR 868.5730
Regulation Name:	Tracheal Tube
Product Code:	BTR
Regulatory Class:	Class II
Predicate Device(s):	K110269-Well Lead Endotracheal Tube with Evacuation Lumen

1. Intended Use

The Endotracheal Tube with Evacuation Lumen is intended for oral intubation and drainage of the subglottic space for airway management.

2. Device Description

The Endotracheal Tube with Evacuation Lumen is sterile, single-use devices supplied with a standard 15mm connector. The Endotracheal Tube with Evacuation Lumen is a Magill curved construction with primary lumen for patient ventilation. Two (2) narrower lumens within the primary wall are used for cuff inflation and subglottic evacuation (vacuum). A low pressure, conformable cuff is inflated through the inflation tube with pilot balloon using a standard syringe (air only) through a non-return valve. For evacuation of subglottic secretions, a separate suction line, with a capped connector, connects to standard hospital vacuum receptacles. The tube incorporates a radiopaque line to assist in radiographic visualization.

The Endotracheal Tube with Evacuation Lumen is PVC (polyvinylchloride) tube with a cylindrical-shaped cuff. The cuff is available with two materials PVC (polyvinylchloride) and PU(polyurethane). It is available in sizes 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 and 9.0mm and consists

of tube, cuff, inflation tube, non-return valve, pilot balloon, 15mm connector, suction line.

The only modification that was made is the materials:
The Endotracheal Tube with Evacuation Lumen differs from the predicate device in that the cuff is made of PVC which are not made with DEHP and PU. The predicate device cuff is made of PVC which contains DEHP. In addition, the materials of the tube (including main tube, inflation tube and suction line) and pilot balloon are modified to PVC which is not made of DEHP.
The PVC materials used for the modified device are not made with DEHP.

The intended use of the modified device, as described in its labeling, has not changed as a results of the modification.

3. Substantial Equivalence—Comparison to Predicate Devices
The predicate device to which we claim equivalence is the Well Lead Endotracheal Tube with Evacuation Lumen (K110269).

The Endotracheal Tube with Evacuation Lumen maintains the same intended use as the predicate device. It is intended for oral intubation and drainage of the subglottic space for airway management. The proposed device and the predicate device consist of the same fundamental technology.

The Endotracheal Tube with Evacuation Lumen differs from the predicate device in that the cuff is made of PVC which are not made of DEHP and PU. The predicate device cuff is made of PVC which contains DEHP. In addition, the materials of the tube (including main tube, inflation tube and suction line) and pilot balloon are modified to PVC which is not made of DEHP.
The PVC materials used for the modified device are not made with DEHP.
The modification has not altered the fundamental scientific technology of the predicate Well Lead Endotracheal Tube with Evacuation Lumen.

Therefore the modified Endotracheal Tube with Evacuation Lumen is substantially equivalent to the current legally marketed Well Lead Endotracheal Tube with Evacuation Lumen (K110269) device. The proposed device is substantially equivalent in intended use, design, performance and principles of operation to the predicate device.
The differences between the Endotracheal Tube with Evacuation Lumen and the predicate device raise no different issues of safety and effectiveness.

A Risk Analysis was conducted and is detailed in the Design Control Summary Section.
No new issues of safety and effectiveness were identified during this process.

The Endotracheal Tube with Evacuation Lumen and the predicate device consist of the same fundamental technology and are sterilized with acceptable methods. Below is a comparison table that summarizes the technological characteristics of the proposed and predicate endotracheal tubes.

Comparison between proposed device and predicate device		
Comparison	**Proposed Device**	**Predicate Device**
Device Name	Endotracheal Tube with Evacuation Lumen	Well Lead Endotracheal Tube with
510k Number	---	K110269
Product Code	BTR	BTR
Regulation Number	21 CFR 868.5730	21 CFR 868.5730
Regulatory Class	Class II	Class II
Classification Pannel	Anesthesiology	Anesthesiology
Indications for Use/ Intended Use	The Endotracheal Tube with Evacuation Lumen is intended for oral intubation and drainage of the subglottic space for airway management.	Same. The Well Lead Endotracheal Tube with Evacuation Lumen is intended for oral intubation and drainage of the subglottic space for airway management.
Anatomical site	The tube is inserted into a patient's tracheal via the oral to maintain an open airway.	Same
Materials		
Main Tube	PVC not made with DEHP	PVC which contains DEHP
Pilot Balloon	PVC not made with DEHP	PVC which contains DEHP
Cuff	PU PVC not made with DEHP	PVC which contains DEHP
Inflation Tube	PVC not made with DEHP	PVC which contains DEHP
Suction Line	PVC not made with DEHP	PVC which contains DEHP
15mm	PP	Same
Design		
Size(ID)	ID6.0mm-ID90.mm	Same
15mm Connector	Yes	Same
Radiopaque Line	Yes	Same
Structure Composition	Main tube, Cuff, Inflation Tube, 15mm Connector, Pilot Balloon, non-return Valve, Suction Line, Suction Line Connector	Same
Supplied Sterile	Yes	Same
Sterilization Method	EO sterilized	Same
Single Use	Yes	Same

4. Summary of Non-Clinical Testing

The following performance testing and biocompatibility testing comparing the modified device to the predicate device was conducted.

- Performance Bench testing has been conducted to verify that the performance of the proposed Endotracheal Tube with Evacuation Lumen is substantially equivalent to the predicate device, and that the Endotracheal Tube with Evacuation Lumen will perform as intended. Bench-top testing was conducted to assure conformance to the following standards:
  - ISO 5361:2016-Anaesthetic And Respiratory Equipment-Tracheal Tubes and Connectors
- The following Biocompatibility testing was performed in accordance with ISO 10993-1
  - Cytotoxicity
  - Sensitization
  - Irritation/Intracutaneous reactivity
  - Acute systemic toxicity
  - Subchronic systemic toxicity
  - Genotoxicity
  - Material-mediate pyrogenicity
  - Implantation
- Sterilization by ethylene oxide has been validated for Endotracheal Tube with Evacuation Lumen
- A risk analysis according to ISO standard "14971 Medical Devices – Application of risk management to medical devices" was carried out for the Endotracheal Tube with Evacuation Lumen. Possible hazards and consequences were systematically identified and evaluated by using the "Failure Mode and Effect Analysis" technique.
- The following bench testing was conducted to support the performance of the Suction Line component of Endotracheal Tube with Evacuation Lumen. The test results demonstrated that the device meets the performance requirements for its intended use:
  - Suction Line O.D. & Length
  - Tensile Force Test (Inflating tube and tracheal tube)
  - Tensile Force Test (Suction tube and the connector of suction tube)
  - Negative Pressure Resistance of Suction Line

Conclusions Drawn from the Non-Clinical Testing

The performance and biocompatibility testing provided in this submission demonstrate that the modified Endotracheal Tube with Evacuation Lumen is as safe and effective and performs as well as the predicate device and therefore supports the determination of substantial equivalence.

5. Conclusion

The Endotracheal Tube with Evacuation Lumen is substantially equivalent to predicate device. Based on the intended use, principle of operation, performance characteristics, and technological characteristics, the proposed Endotracheal Tube with Evacuation Lumen is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate device.