K110269

AUG 2 6 2011

Traditional 510(k) Summary

(as required by 807.92(c))

Regulatory Correspondent:

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Submitter of 510(k):

WELL LEAD MEDICAL CO. LTD
C-4 JINHU INDUSTRIAL ESTATE, HUALONG, PAN YU
GUANGZHOU, 511434, CHINA

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Contact Person: Han Guang Yuan

510(k) Preparation Date: 12/27/2010

Device Name:

Trade Name: Well Lead Endotracheal Tube with Evacuation Lumen
Common Name: Endotracheal Tube with Evacuation Lumen
Classification Name: Tube, tracheal (w/wo connector) (21 CFR 878.5730, Product Code FMC73 BTR)

Predicate Device:

K042683–WELL LEAD ENDOTRACHEAL TUBE
K090352–Taperguard Evac™ Endotracheal Tubes

Device Description:

Well Lead Endotracheal Tube with Evacuation Lumen-Oral (6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm)
The Well Lead Endotracheal Tube with Evacuation Lumen is sterile; single-use devices supplied with a standard 15mm connector. It is made of Polyvinylchloride. In addition to the main lumen, the tube has a separate lumen which has a dorsal opening above the cuff. Access to the lumen is accomplished via a clear connecting tube with a capped Luer connector. The tube incorporates a Magill curve, a tip with Murphy Eye and a radiopaque line to assist in radiographic visualization.

Intended Use:

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

Substantial Equivalence:

Well Lead Medical Instruments claims the proposed device is substantially equivalent to the devices previously cleared by FDA, K042683 and K090352.

The Well Lead Endotracheal Tubes with Evacuation Lumen maintain the similar intended use as the predicate device. It is a device inserted into the trachea to facilitate breathing.

The Well Lead Endotracheal Tubes with Evacuation Lumen and the predicate device consist of the same fundamental technology.

The Well Lead Endotracheal Tubes with Evacuation Lumen differ from the predicate device K042683 in that it has a Evacuation Lumen for evacuation for drainage of the subglottic space.

The Well Lead Endotracheal Tubes with Evacuation Lumen differ from the predicate device K090352 in that the cuff is in different shape.

The Well Lead Endotracheal Tubes with Evacuation Lumen in clinical application will be identical to the use of predicate device K090352. None of the changes in any way affect the operation or usability of the tube or cuff.

Summary of Non-Clinical Data

The results from non – clinical data were provided for the Endotracheal Tubes with Evacuation lumen according to EN1782:1998 and ISO 5361-1:1999, in each of the tests the results fell within the required limits of the standard. The following testing was performed:

Surface Finish
Dimensions Testing (I.D, O,D Overall Length)
Connector Testing
Cuff Heniation
Cuff Resting Diameter
Tube Collapse
Tube Inflation
Radius of curvature
Angle of bevel
Security of the construction of the evacuation lumen
Shaft of the evacuation lumen

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Well Lead Medical Company, Limited
C/O Mr. John O'Brien
Regulatory Affairs Specialist
AJW Technology Consultants, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

AUG 26 2011

Re: K110269
Trade/Device Name: Well Lead Endotracheal Tube with Evacuation Lumen
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR, BSY
Dated: August 4, 2011
Received: August 22, 2011

Dear Mr. O'Brien:

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.

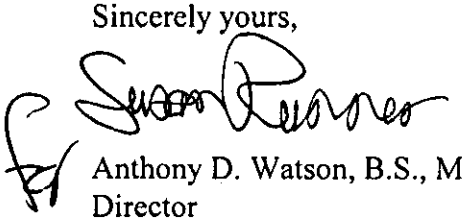
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110269

Device Name: Well Lead Endotracheal Tube with Evacuation Lumen

Indications for use:

The device is intended for Oral intubation and drainage of the subglottic space for airway management.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110269