K042683

FEB 18 2005

510K SUMMARY FOR ENDOTRACHEAL TUBE

SUBMITTER NAME: Well Lead Medical Instruments Ltd

SUBMITTER ADDESS: Jinhu Industrial Estate, Hualong, Panyu, Guangzhou City, China

CONTACT PERSON: Huan Guang Yuan (vice general manager)

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EMAIL: han@welllead.com.cn

DATE PREPARED: July 16, 2004

TRADE NAME: well lead Endotracheal tube

COMMON NAME: ET-tube

CLASSIFICATION NAME: Tracheal tube

CLASSIFICATION: BTR

PREDICATE DEVICE: Well Lead is claiming substantial equivalence to the following medical device(s) -

- Kendall – Pre-Amendment
- RÜSCHELIT – K961837, K993786, K961840, K931163, K93786

DEVICE DESCRIPTION: The tracheal tubes are made from medical grade PVC, with a connector and valve. The tracheal tubes may be cuffed or uncuffed and are for oral or nasal use.

INTENDED USE: The device is intended for oral or nasal intubation and for airway management.

DEVICE PERFORMANCE: the dimension, design, material, sterility and packaging of well lead endotracheal tube are conformed with ISO 5361:1999(E)

DEVICES COMPARE: the device has the same dimensions and design as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Well Lead Medical Instruments Limited
C/O Mr. Arthur J. Ward
Regulatory Consultant
AJW Technology Consultants, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K042683
Trade/Device Name: Well Lead Endotracheal Tube
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: January 3, 2005
Received: January 6, 2005

Dear Mr. Ward:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K042683
Device Name: Endotracheal Tube
Indication For Use:

The device is intended for oral or nasal intubation and for airway management.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K042683