K073383

JUL 10 2008

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): **Well Lead Medical Instruments**
A4-1# Jinhu Industrial Estate
Hualong, Pan Yu
Guangdong, China 511434

Phone: 8620 84752978
Fax: 8620 84758224

Contact Person: Han Guang Yuan

Date of Summary: September 13, 2007

Trade/Proprietary Name: Well Lead Reinforced Endotracheal Tube

Classification Name: Tube, Tracheal (w/wo connector)

Product Code: BTR

Intended Use:

The Well Lead Reinforced Endotracheal Tubes are designed for oral or nasal intubation for airway management during anaestesia. The product may be used where the patient's neck is likely to be moved or flexed or the patient is in the prone positiom so that a non-reinforced tracheal tube might become kinked.

Device Description:

Single Use.

A Tracheal tube with addidional metal wire spiral reinforcement to provide kink-resistance. This type of product is typically used during operations where a high degree of flexibility is required from the tube, for instance prone position, head and neck surgery, and oral surgery.

The plastic material and the spring allow the tube to be easily bent in all directions. The steel reinforcement maintains the patency of the lumen.

The Well Lead Reinforced Endotracheal tube is available in cuffed and uncuffed variants. The cuff is intended to provide a seal against the trachea, ensuring that inspiratory and expiratory gasses are routed through the tube and not allowed to escape to the patients upper airway, thus

preventing loss of ventilation / anaesthetic and nebulised drugs, and reducing the likelihood of any aspirated stomach contents from entering the lungs. Uncuffed tubes are used mainly for paediatric patients or when patients require less protection from loss of ventilation / anaesthetic and nebulised drugs and or stomach aspiration.

The Reinforced Endotracheal tube (Cuffed) is available in sizes 5.0, 5.5, 6.0, 6.5, 7.0, 8.0, 8.5, 9.0, and 9.5 mm only.
The Reinforced Endotracheal tube (Uncuffed) is available in sizes 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, and 9.5 only

Device Performance:

The dimension, design, material, sterility and packaging of Well Lead Reinforced Endotracheal Tube are conformed with ISO 5361:1999(E) except the tolerance of the outside diameter.

Predicate Device:

K032112 – Portex Reinforced Tracheal Tube (Cuffed and Uncuffed)
K042683 Well Lead Endotracheal Tube

Substantial Equivalence:

Well Lead Medical Instruments claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in K032112. Well Lead Medical Products claims this equivalence because the proposed devices have an equivalent intended use, manufacturing materials, operating principles, and physical, operational specifications as compared to the predicate devices. In addition this 510(k) is a variation of the already cleared Well Lead 510(k) K042683 with a wire reinforcement added.

The similarities and differences between the proposed and predicate devices have been identified and explained in the Comparison Matrix which has been included in Section 9 of this submission. Additionally, this matrix is included as an attachment to the 510(k) Summary. These differences have no effect on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2008

Well Lead Medical Instruments
C/O Dr. Arthur J. Ward
Regulatory Correspondent
AJW Technology Consultants, Incorporated
962 Allergo Lane
Apollo Beach, Florida 33572

Re: K073383
Trade/Device Name: Well Lead Reinforced Endotracheal Tubes
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: June 24, 2008
Received: June 30, 2008

Dear Dr. 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) 276-0120. 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

Indications for Use

510(k) Number (if known): _____

Device Name: Well Lead Reinforced Endotracheal Tubes

Indication for use:

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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

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