K042684

FEB 17 2005

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

Submitter of 510(k):	Well Lead Medical Instruments Ltd Jinhu Industrial Estate, Hualong, Panyu, Guangzhou City, China 511434 Phone: +8620 84752978 Fax: +8620 84758224
Contact Person:	Huan Guang Yuan, han@welllead.com.cn
Date of Summary:	October 1, 2004
Trade/Proprietary Name:	Well Lead Tracheostomy Tubes
Classification Name:	Tracheostomy Tube
Product Code:	BTO
Predicate Device:	Rusch Tracheofix Set, Cuffed and Uncuffed - K021764
Intended Use:	The device is a single patient disposable tracheostomy tube for airway management of tracheostomotized patients.

Device Description:

The tracheostomy tubes are made from the raw material of PVC for medical use, with the component of connector and valve. The tracheostomy tubes have such good performances as the tube with appropriate hardness, the cuff with big capacity and low pressure, smooth tube and excellent biocompatibility.

Device Performance:

The dimension, design, material, sterility and packaging of Well Lead tracheostomy tubes are conformed with ISO 5366-1 and ISO 5366-3.

Device Comparison: The device has the same dimensions and design as the predicate device (Section 9).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 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: K042684
Trade/Device Name: Well Lead Tracheostomy Tube
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: BTO
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) 276-0120. 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,

Juliette Y. Mahaim MD

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): K042684

Device Name: Well Lead Tracheostomy Tubes

Indications for Use: The device is a single patient disposable tracheostomy tube for airway management of tracheostomotized patients.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lilia Johnson

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

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