K 101721

MAR 2 4 2011

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

Regulatory Correspondent:

AJW Technology Consultants Inc
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Submitter of 510(k):

Well LEAD Medical Device Instruments Ltd.
A4-1# Jinhu Industrial Estate
Hualong, Panyu
Guangzhou City, China 511434
Han Guang Yuan
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Date of Summary: November 29, 2010

Trade/Proprietary Name: Well Lead Tracheostomy Tubes and Disposable Inner Cannula

Classification Name: Tracheostomy Tube and Tube Cuff

Product Code: BTO

Intended Use:

The Well lead Tracheostomy Tubes and Disposable Inner Cannula is a single patient disposable tracheostomy tube for airway management of tracheostomotized patients.

Device Description:

The Well lead Tracheostomy Tubes and Disposable Inner Cannula includes an outer cannula, disposable inner cannula, introducer, neck strap and obturator. The disposable inner cannula acts as a removable liner for the outer tube; it can be.withdrawn and changed after the airway has been cleaned, such as phlegm suction. The disposable inner cannula facilitates the airway management to make it easy to clean and prolong the use of the device. The device is used to provide an artificial airway in order to provide access to the patient's airway for airway management. The device is introduced into a tracheotomy incision in the patient's neck that provides access to the trachea. The tracheostomy tube is

secured by the means of the swivel neck plate/flange. When appropriately connected the device provides a secure artificial airway for spontaneous or mechanical ventilation.

Predicate Device: K042684 – Well Lead Tracheostomy Tubes

Substantial Equivalence:

The proposed device is substantial equivalent to the Well Lead Tracheostomy Tubes, which has been cleared under K042684. The proposed device has the same intended use and similar technological characteristics as compared to the predicate device.

Device Performance:

The dimension, design, material, sterility and packaging of Well Lead Tracheostomy Tubes and Disposable Inner Cannula conform to ISO 5366-1 and 5366-2.

Comparison of Technological Characteristics

The intended use of the modified device remains unchanged as does its risk classification. The modified device will continue to be indicated for the same patient population and will continue to be a prescription device. Both devices are intended to be a component of life sustaining devices which are to be used for airway management.

Both Well Lead Tracheostomy Tubes and Disposable Inner Cannula and Well Lead Tracheostomy Tube have the same intended use, there is no new indications or contraindications.

Both the modified and unmodified device include an outer cannula, introducer, neck strap. A disposable inner cannula and obturator are being added to the modified device, both devices continue to have cuffed and uncuffed versions.

For fixing the inner cannula to the outer cannula a locking mechanism has been designed. As part of this design the component material has not changed.

Conclusions:

In summary, Well Lead Medical Instruments Ltd has demonstrated that Well Lead Tracheostomy Tubes and Disposable Cannula is safe and effective. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

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

Mr. Arthur Ward
Regulatory Correspondent
AJW Technology Consultants, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

MAR 24 2011

Re: K101721
Trade/Device Name: Well Lead Tracheostomy Tubes and Disposable Inner Cannula
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: BTO
Dated: March 3, 2011
Received: March 15, 2011

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. 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,

for

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): K101721

Device Name: Well Lead Tracheostomy Tubes and Disposable Inner Cannula

Indication for Use:

The Well Lead Tracheostomy Tubes and Disposable Inner Cannula is a single patient disposable tracheostomy tube for airway management of tracheostomotized patients.

Prescription Use X (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)

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

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