510(k) SUMMARY
K 092886
(as required by 807.92(c))

MAR 11 2010

Regulatory Correspondent:

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Submitter of 510(k):

Well LEAD Medical Device Instruments Ltd.
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Date of Summary: 3/11/2010

Trade/Proprietary Name: Well LEAD Endobronchial Tubes

Classification Name: Endobronchial Tubes

Product Code: CBI

Intended Use: The Well Lead Endobronchial Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

Device Description: The Well Lead Endobronchial Tube is made of Polyvinylchloride and is available in sizes 28fr to 41fr. They are designated as double lumen tube with 2 cuffs and separate 15mm connectors for isolating and ventilating one lung during surgical procedures. The tubes contain an x-ray opaque line that runs through the tube making them detectable by x-ray.

Predicate Device: K771219 – Mallinckrodt Bronch-Cath
K051522 – Fuji Double Lumen Bronch Tube

Substantial Equivalence:

Well Lead Medical Instruments claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in K771219. Well Lead Medical Instruments 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. 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 10 of this submission. These differences have no effect on safety and effectiveness.

Performance Testing:

All testing that is required by the required standards has been performed. None clinical testing was performed and included standards such as ISO 5361, ISO 16628 and ISO 10993-1. The Well Lead Medical Instruments Endobronchial Tubes have been found to fall within the required limits of the testing. The test results can be found in both the Biocompatibility Testing (Section 13) and the Performance Testing (Section 14) of this submission. Therefore we have concluded that the Well Lead Endobronchial Tubes are substantially equivalent.

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 Device Instruments Limited
C/O Dr. Arthur J. Ward
Regulatory Correspondent
Regulatory and Marketing Services, Incorporated
962 Allergo Lane
Apollo Beach, Florida 33572

MAR 11 2010

Re: K092886
Trade/Device Name: Well Lead Endobronchial Tubes
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: March 3, 2010
Received: March 9, 2010

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. 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): K092886

Device Name: Well Lead Endobronchial Tubes

Indications for Use: The Well Lead Endobronchial Tube is used to isolate the left or the right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

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

510(k) Number: K092886

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)