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

APR 30 2010

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Date of Summary: June 26, 2009

Trade/Proprietary Name: Vibrolith and Vibrolith PLUS Intracorporeal Lithotriptor

Classification Name: Electrohydrolic Lithotriptor

Product Code: 78 FFK

Regulation Number: 876.4480

Intended Use: This unit is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.

Device Description: The ELMED Vibrolith Plus® is intracorporeal lithotripter which joint together the ultrasonic lithotripter with aspiration system with the high efficiancy of the electro-pneumatic lithotripter. Three possible modes of operation are available using Vibrolith Plus® such as; (1) pneumatic lithotripsy alone; (2) ultrasonic lithotripsy alone; (3) and combined pneumatic and ultrasonic lithotripsy.

The system consists of two independent operating units in one housing, which allows for independent operation of the two modalities. Delivery of energy is controlled using a common two-pedal footswitch.

The pneumatic part of the system works under the principle of collision of a bullet, accelerated by a medical compressed air supply from either a compressor or a central hospital supply. The compressed air provides the pressure pulse that drives the projectile

within pneumatic handpiece toward the proximal end of the probe. This probe transmits the impact energy to the stone, resulting in fragmentation. By this electro-pneumatic ballistic energy, only the calculi is disintegrated, there is no effect on tissue.

The pneumatic part can also be used in combination with aspiration system. The pneumatic probes can be inserted through the suction tube for simultaneous lithotripsy and suction.

The ultrasonic lithotriptor works under the principle of vibration in the ultrasonic area by the piezo-ceramic crystals and transmites these vibrations to the stone with a steel probe inserted into the body by endoscopy.

The endoscope is used to position the Vibrolith Plus® handpiece in the urethra under direct observation.

The ultrasonic handpiece consists of an ultrasound transducer containing the piezoelectric elements, which are driven by a generator operating between 15-28 kHz. The resulting longitudinal waves are propagated along the ultrasound probe to the target stone. The ultrasound transducer and the probes are hollow, permitting simultaneous suction.

Combined operation of the pneumatic and ultrasonic parts is desirable for certain hard kidney and bladder stones. In order to use the combined energy, the pneumatic and ultrasonic handpieces must be mounted together. In a combined operation, the probes must be length-adjusted so that the tip of the pneumatic probe is flush with the tip of the ultrasonic probe.

The Vibrolith Plus® is designed to be used with general or spinal anesthesia. This design, together with the clinical data, offers a particular advantage for using Vibrolith Plus® in patients with renal, ureteral and bladder stones. This advantage may be most significant in patients who wish to remain physically active and for those who are in higher risk categories where serious side effects present a significant threat to their health and well being.

For the application, probes with various lengths and in various diameters are available, which permits adaptation to the stone size as well as to the available lumen of the working channel.

The ELMED Vibrolith is very similar to the Vibrolith Plus with the exception that the Vibrolith is only available with pneumatic lithotripsy.

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Predicate Device:	EMS Swiss Lithocast Master – K012445 EMS Swiss Lithocast 2 – K963285
Substantial Equivalence:	The Vibrolith Plus is substantially equivalent to the Swiss Lithocast Master, which has been cleared for both pneumatic and ultrasonic lithotripsy and the Vibrolith is substantially equivalent to the Swiss Lithocast 2 which has been cleared for pneumatic lithotripsy. The proposed devices have the same intended use and similar technological characteristics as compared to the predicate device.

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

APR 30 2010

Elmed USA
% Mr. Jonathan Ward
Vice-President
AJW Technology Consultants, Inc.
962 Allegro Lane
APOLLO BEACH FL 33572

Re: K092033
Trade/Device Name: Vibrolith and Vibrolith Plus Intracorporeal Lithotriptor
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: March 16, 2010
Received: March 18, 2010

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 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092033

Device Name: Vibrolith and Vibrolith Plus Intracorporeal Lithotriptor

Indications for Use: This unit is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.

Prescription Use **Yes** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **No** (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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K092033