K032958

FEB 17 2004



# 510(k) SUMMARY

## UMS's Piezolith 3000 Lithotripter

### Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

United Medical Systems
One Technology Drive, Third Floor
Westborough, MA 01581
Tel: (800) 516-9425
Fax: (508) 870-0682
**Registration Number:** 1226692

Contact Person: Jorgen Madsen

Date Prepared: September 17, 2003

### Name of Device and Name/Address of Sponsor

Piezolith 3000 Lithotripter

United Medical Systems
One Technology Drive, Third Floor
Westborough, MA 01581

### Common or Usual Name

Extracorporeal Shock Wave Lithotripter

### Classification Name

Extracorporeal Shock Wave Lithotripter

### Predicate Devices

Richard Wolf Piezolith E.P.L. Lithotripter, Model 2300
Dornier Compact S
Dornier Compact Delta
Siemens Modularis Litho
Storz Modulith SLX
Storz Modulith SLK

## Intended Use / Indications for Use

The Piezolith 3000 is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

## Technological Characteristics

The Piezolith 3000 is comprised of the following principal components: (1) a shock wave generator, which includes an adjustable therapy head/coupling mechanism mounted on an articulating arm or (when X-ray imaging is used) mounted to a swivel slide on C-arm; (2) a control console; (3) an X-ray; (4) ultrasound imaging system for localization; and (5) a treatment table.

## Substantial Equivalence

The Piezolith 3000 is substantially equivalent to the other currently marketed lithotripters which are referenced above. The Piezolith 3000 and its predicate devices are all extracorporeal shock wave lithotripters. Thus, the Piezolith 3000 raises no new issues of safety or effectiveness.

## Performance Data

The company performed shock wave characterization measurements, localization accuracy measurements, and road testing. In addition, the Piezolith 3000 system was tested according to and conforms with the following voluntary consensus standards: (1) IEC 60601-1: 1988 with Amdt 1, 1991 and Amdt 2, 1995 "Medical electrical equipment," (2) IEC 60601-1-1: 1992 with Amdt 1, 1995 "Medical electrical equipment; Part 1: General requirements for safety," (3) IEC 60601-1-2: 1993 "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests; 62A/336/FDIS", (4) CISPR 11: 1990 "Limits and Methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment," (5) IEC 60601-2-36: 1997 "Medical electrical equipment; Part 2 Particular requirement for the safety of equipment for extracorporeally induced lithotripsy," and (6) as reference for the measurements: IEC 61846: 1998 "Ultrasonic - Pressure pulse lithotripters - Characteristics of field." In addition, clinical data demonstrated that the device is substantially equivalent to its predicate devices. In all instances, the Piezolith 3000 functioned as intended and performed as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2004

United Medical Systems, Inc.
c/o Jeffrey K. Shapiro
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
WASHINGTON DC 20004-1109

Re: K032958
Trade/Device Name: Piezolith 3000 Lithotripter
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: December 17, 2003
Received: December 17, 2003

Dear Mr. Shapiro:

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); 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 one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
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): **K032958**

Device Name: **United Medical Systems, Inc. Piezolith 3000 Lithotripter**

Indications for Use: **The Piezolith 3000 is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).**

Prescription Use ___✓___ ~~AND~~/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (Part 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032958