K062081

Section 5: 510(k) Summary

NOV - 2 2006

Sponsor: Tissue Regeneration Technologies
110 Arnold Mill Park, Suite 400
Woodstock, Georgia 30188

Manufacturer: MTS Europe GmbH
Robert-Bosch-Str. 18
D-78467 Konstanz, Germany

Contact: Cherita James
M Squared Associates, Inc
719 A Street, NE
Washington, DC 20002
Ph: 202-546-1262 Ext 257
Fax: 202-546-3848

Date of submission: July 21, 2006

Proprietary Name: LithoGold

Common name: Extracorporeal shock wave lithotriptor

Recommended classification regulation: 876.5990

Class: II

Panel: Gastroenterology/Urology Devices

Product Code: LNS

Intended Use: The LithoGold is an extracorporeal shock wave lithotripsy device intended to fragment urinary stones in the kidney (renal pelvis and calyces) and ureter (upper, middle and lower).

Predicate device: HealthTronics LithoTron (P970019)

Device description: The LithoGold is an extracorporeal shock wave therapy device designed for the non-invasive fragmentation of urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle and lower ureter). The LithoGold employs an electrohydraulic method of shock wave generation with both ECG gating and fixed frequency capabilities.

The LithoGold unit will be combined with the Modularis Uro Plus (table) and Arcadis

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Varic (C-arm) or Siremobil Compact L (C-arm), all products manufactured by Siemens Medical Solutions, Inc.; and the ECG Monitor Infinity Gamma (ECG) manufactured by Draeger Medical systems, Inc. These components have each been cleared for distribution in the U.S.

Summary of non-clinical testing: Testing in accordance with "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi (2000)" has been successfully completed. The LithoGold acoustic qualities have been measured using the methodology described in the consensus standard IEC 61846 "Ultrasonics - Pressure pulse lithotripters - Characteristics of fields" (1998). Additionally, the device has been found to conform to recognized consensus standards for electrical and EMC testing.

Summary of clinical testing:

The confirmatory clinical study showed that the LithoGold ESWL system is expected to treat patients with renal or ureteral calculi with safety and effectiveness outcomes substantially equivalent to those for predicate lithotripsy devices.

Basis for Substantial Equivalence: Both the LithoGold and the predicate device have similar technical design features and indications for use. Bench testing and clinical testing confirm the substantial equivalence of the LithoGold to the LithoTron extracorporeal shock wave delivery system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Tissue Regeneration Technologies, Inc.
c/o Ms. Cherita James
Regulatory Consultant
M Squared Associates, Inc.
719 A Street, N.E.
WASHINGTON DC 20002

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Re: K062081
Trade/Device Name: LithoGold
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: September 12, 2006
Received: September 13, 2006

Dear Ms. James:

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

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Indications for Use

510(k) Number (if known): ~~not yet assigned~~ K062081

Device Name: LithoGold

Indications For Use: The LithoGold is an extracorporeal shock wave lithotripsy device intended to fragment urinary stones in the kidney (renal pelvis and calyces) and ureter (upper, middle and lower).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062081