SECTION 3 – 510 (K) SUMMARY

Submitter's information

Name

Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway
Malvern, PA 19355

Contact Person:

Name:	Debbie Peacock
Title:	Technical Specialist, Regulatory Affairs
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Date summary prepared

10/13/03

Device names

Trade Name

LITHOSTAR MODULARIS with Shockwave System C_{plus}

Common or Classification Name

LITHOSTAR MODULARIS

A. Legally marketed device to which the device is substantially equivalent

The predicate device is the Siemens LITHOSTAR MODULARIS, P870018, Supplement 21.

B. Description of device

Siemens LITHOSTAR MODULARIS with Shockwave System C_{plus} is a modification to our predicate device. The shockwave head has been modified to provide an increased penetration depth for a more obese patient population. The penetration depth has been increased from 120mm to 140mm..

C. Indications for Use

LITHOSTAR MODULARIS with Shockwave System C_{plus} is a urologic procedures system which can be used for a wide range of applications. It is a transportable system. The system is capable of both diagnostic and therapeutic procedures of urolithiasis in the kidney and upper ureter. The primary use of this device is for the fragmentation of urinary tract stones, i.e. renal calyceal stones, renal pelvis stones, and upper ureteral stones by extracorporeal shockwave lithotripsy (ESWL). In addition to ESWL use, the unit is designed for patient placement in positions which facilitate urological and diagnostic procedures.

D. Contraindications

Do not use the LITHOSTAR MODULARIS in patients with:

- Confirmed or suspected pregnancy.
- Coagulation abnormalities (as indicated by abnormal prothrombin time, partial thromboplastin time, or bleeding time) or those currently receiving anticoagulants (including aspirin).
- Arterial calcification or vascular aneurysm in the lithotripter's shockwave path.
- Urinary tract obstruction distal to the stone.
- Anatomy which precludes focusing the device at the target stone, such as severe obesity or excessive spinal curvature.

E. Warnings and Precautions

A listing of Warnings and Precautions are included in labeling.

F. Technological characteristics

The modification has not altered the fundamental technology of the predicate device.

G. Assessment of non-clinical performance data

Device shockwave parameters were measured and documented according to Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shockwave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi..

H. Assessment of clinical performance data

The confirmatory clinical study suggests that treatment of urinary tract stones with the LITHOSTAR MODULARIS with Shockwave System C_{plus} is safe and effective and comparable to the currently approved LITHOSTAR MODULARIS (P870018, Supplement 21).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 2003

Ms. Debra A. Peacock
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway
MALVERN PA 19355

Re: K033335
Trade/Device Name: Lithostar Modularis with Shockwave System C_{plus}
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal Shock Wave Lithotripters, Urological
Regulatory Class: II
Product Code: 78 LNS
Regulation Number: 21 CFR§ 876,4890
Regulation Name: Urological Table and Accessories
Regulatory Class: II (Exempt)
Product Code: 78 MMZ
Dated: November 17, 2003
Received: November 18, 2003

Dear Ms. Peacock:

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

SECTION 2 INDICATIONS FOR USE

510(k) Number (if known): K033335
Device Name: LITHOSTAR MODULARIS WITH SHOCK WAVE SYSTEM C_{plus}

Indications For Use:

LITHOSTAR Modularis with Shockwave System C_{plus} is a urologic procedures system which can be used for a wide range of applications. It is a transportable system. The system is capable of both diagnostic and therapeutic procedures of urolithiasis in the kidney and upper ureter. The primary use of this device is for the fragmentation of urinary tract stones, i.e. renal calyceal stones, renal pelvis stones, and upper ureteral stones by extracorporeal shock wave lithotripsy (ESWL). In addition to ESWL use, the unit is designed for patient placement in positions which facilitate urological and diagnostic procedures.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033335