

MODULARIS Variostar 510(k)
Siemens Medical Solutions USA, Inc.

K070799

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510 (k) Summary

Submitter's information

Name

Siemens Medical Solutions, Inc. USA
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Malvern, PA 19355

Contact Person:

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Date summary prepared

10/30/2007

Device names

Trade Name:

MODULARIS Variostar

Common or Classification Name:

Extracorporeal shockwave lithotripter

Legally marketed device to which the device is substantially equivalent

LITHOSTAR Modularis

Description of device

Siemens MODULARIS Variostar is a modified lithotripter featuring a patient table, a C-arm with X-ray tube assembly attached to one end, an image intensifier to the other end and a shockwave system adjacent to the x-ray tube. The shockwave system can be coupled with the patient in various positions providing a high flexibility. For positioning of the shockwave focus there will be fluoroscopy and ultrasound imaging provided. The system is intended for stationary and trans-mobile use.

Indications for Use

MODULARIS Variostar is a lithotripter device designed to treat urolithiasis with extracorporeal shock wave lithotripsy (ESWL) when used as part of the modular platform, MODULARIS.

The device may be used in two separate configurations. Both configurations are designed to support urologic procedures within the scope of urolithiasis and may be used in a mobile-use environment.

Each configuration includes: the lithotripter MODULARIS Variostar with shockwave head C_{plus}, a patient table, and an ECG device.

One configuration would include a mobile C-arm to provide the imaging and positioning of the shockwave focus to the urinary tract stones. This configuration may be used to treat renal calyceal stones, renal pelvis stones, and ureteral stones.

A second configuration would include an ultrasound system to provide the imaging and positioning of the shockwave focus to the urinary tract stones. For this configuration, the indication for use is limited to the fragmentation of kidney and upper ureteral stones only.

Contraindications

Do not use the MODULARIS Variostar 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.

Warnings, Precautions, Adverse Events

Warnings

- **Anticoagulants:**
Patients receiving anticoagulants (including aspirin) should temporarily discontinue such medication prior to extracorporeal shock wave lithotripsy to prevent severe hemorrhage.
- **Cardiac monitoring:**
Always perform cardiac monitoring during lithotripsy treatment, since the use of extracorporeal shock wave lithotripsy has been reported to cause ventricular cardiac arrhythmias in some individuals.
This warning is especially important for patients who may be at risk of cardiac arrhythmia due to a history of cardiac irregularities or heart failure.
- **Pacemaker or implantable defibrillator:**
To reduce the incidence of malfunction to a pacemaker or implantable defibrillator, the pulse generator should be programmed to a single chamber, non-rate responsive mode (pacemakers) or an inactive mode (implantable defibrillators) prior to lithotripsy, and evaluated for proper function post-treatment. Do not focus the lithotripter's shock wave through or near the pulse generator.
- **Infected stones:**
Prophylactic antibiotics should be administered prior to treatment whenever the possibility of stone infection exists.
Extracorporeal shock wave lithotripsy treatment of pathogen-harboring calculi could result in systemic infection.
- **Cardiac disease, immunosuppression, and diabetes mellitus:**
Prophylactic antibiotics should be administered prior to extracorporeal shock

wave lithotripsy treatment to patients with cardiac disease (including valvular disease), immunosuppression, and diabetes mellitus, to prevent bacterial and/or subacute endocarditis.

- **Bilateral stones:**
Do not perform bilateral treatment of kidney stones in a single treatment session, because either bilateral renal injury or total urinary tract obstruction by stone fragments may result. Patients with bilateral kidney stones should be treated using a separate treatment session for each side. In the event of total urinary obstruction, corrective procedures may be needed to assure drainage of urine from the kidney.
- **Air-filled interfaces in shock wave path:**
Do not apply shock waves to air-filled areas of the body, i.e., intestines or lungs. Shock waves are rapidly dispersed by passage through an air-filled interface, which can cause bleeding and other harmful side effects.
- **Cardiac arrhythmia during treatment:**
If a patient experiences cardiac arrhythmia during treatment at a fixed shock wave repetition rate, shock wave delivery should either be terminated or switched to an ECG-gated mode (i.e., delivery of the shock wave during the refractory period of the patient's cardiac cycle). As a general practice, patients with a history of cardiac arrhythmia should be treated in the ECG-gated mode.

Precautions

- **Impacted or embedded stones:**
The effectiveness of extracorporeal shock wave lithotripsy may be limited in patients with impacted or embedded stones. Alternative procedures are recommended for these patients.
- **Staghorn stones:**
The effectiveness of extracorporeal shock wave lithotripsy may be limited in patients with either staghorn or large (> 20 mm in largest dimension) stones. Alternative procedures are recommended for these patients.
- **Small ureteral stones:**
Small middle and lower ureteral stones, 4 to 6 mm in largest dimension, are likely to pass spontaneously. Therefore, the risks and benefits of extracorporeal shock wave lithotripsy should be carefully assessed in this patient population.
- **Renal injury:**
To reduce the risk of injury to the kidney and surrounding tissues, it is recommended that:
the number of shock waves administered during each treatment session be minimized;
retreatment to the same kidney/anatomical site occur no sooner than 1 month after the initial treatment;
each kidney/anatomical site be limited to a total of three treatment sessions.
- **Use of fluoroscopy:**
While fluoroscopy must be used during the procedure, caution should be used to minimize the exposure.
- **Electromagnetic interference:**
If electromagnetic interference between the extracorporeal shock wave lithotripter

and nearby electronic equipment is suspected (as evidenced by erratic behavior with either device), it is recommended that their distance be increased until proper operation resumes. If it is necessary to operate an electronic device in close proximity to the lithotripsy system during treatment, the device and the lithotripter should be tested for proper simultaneous operation prior to clinical use.

- **Radiographic follow-up:**
All patients should be followed radiographically after treatment until stone-free or there are no remaining stone fragments which are likely to cause silent obstruction and loss of renal function.
- **Electrical shock hazard:**
Never remove any of the cabinet covers to the system's electronics. The high voltage power supply circuits utilized by extracorporeal shock wave lithotripters use voltages that are capable of causing serious injury or death from electric shock.

Adverse Events

Potential adverse events associated with the use of extracorporeal shock wave lithotripsy include those listed below, categorized by frequency and individually described:

Commonly reported (> 20% of patients)

- o Hematuria
- o Pain/renal colic
- o Skin redness at shock wave entry side

Occasionally reported (1 - 20% of patients)

- o Cardiac arrhythmia
- o Urinary tract infection
- o Urinary obstruction/steinstrasse
- o Skin bruising at shock wave entry side
- o Fever (> 38°C)
- o Nausea/vomiting

Infrequently reported (< 1% of patients)

- o Hematoma (perirenal/intrarenal)
- o Renal injury

Hematuria occurs following most treatments, is believed to be secondary to trauma to the renal parenchyma, and usually resolves spontaneously within 24 to 48 hours of treatment.

Pain/renal colic commonly occurs during and immediately after treatment, and typically resolves spontaneously. Temporary pain/renal colic may also occur secondary to the passage of stone fragments, and can be managed with medication.

Skin redness at shockwave entry site commonly occurs during and immediately after treatment, and typically resolves spontaneously.

Cardiac arrhythmia, most commonly premature ventricular contractions, are generally reported during extracorporeal shock wave lithotripsy at fixed shock wave delivery in 2 to 20% of patients. These cardiac disturbances rarely pose a serious risk to the healthy

patient, and typically resolve spontaneously upon synchronizing the shock waves with the refractory period of the ventricular cycle (i.e., ECG gating) or terminating treatment. **Urinary tract infection** Urinary tract infection (UTI) occurs in 1 - 7% of patients following extracorporeal shock wave lithotripsy as a result of the release of bacteria from the fragmentation of infected calculi, and infrequently results in pyelonephritis or sepsis.

The risk of infectious complications secondary to extracorporeal shock wave lithotripsy can be minimized through the use of prophylactic antibiotics in patients with UTI and infection stones.

Urinary obstruction/steinstrasse occurs in up to 6% of patients following lithotripsy due to stone fragments becoming lodged in the ureter, and may be the result of either a single stone fragment or the accumulation of multiple small stone particles (i.e., steinstrasse). Patients with urinary obstruction typically present with persistent pain, and may be at risk of developing hydronephrosis with subsequent renal failure if the obstruction is not promptly treated. Intervention is necessary if the obstructing fragments do not pass spontaneously.

Skin bruising at shock wave entry site occasionally occurs after treatment, and typically resolves spontaneously.

Fever (> 38°C) is occasionally reported after lithotripsy, and may be secondary to infection.

Nausea/vomiting - Transient nausea and vomiting are occasionally reported immediately after lithotripsy, and may be associated with either pain or the administration of sedatives or analgesia.

Hematoma (perirenal/intrarenal) - Clinically significant intrarenal or perirenal hematomas occur in < 1% of lithotripsy treatments. These patients typically present with severe, chronic flank pain. Although clinically significant hematomas often resolve with conservative management, severe hemorrhage and death have been reported. Management of severe renal hemorrhage includes the administration of blood transfusions, percutaneous drainage, or surgical intervention.

Renal injury - Extracorporeal shock wave lithotripsy procedures have been known to cause damage to the treated kidney. The potential for injury, its long-term significance, and its duration are unknown.

A. Technological characteristics

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

B. 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 in K033337. MODULARIS Variostar features the same shockwave head and generator as the predicate device LITHOSTAR Modularis.

C. Assessment of clinical performance data

The confirmatory clinical study suggests that treatment of urinary tract stones with the MODULARIS Variostar is safe and effective.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2007

Ms. Kim Rendon
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K070799
Trade/Device Name: MODULARIS Variostar
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: September 27, 2007
Received: September 28, 2007

Dear Ms. Rendon:

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 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.

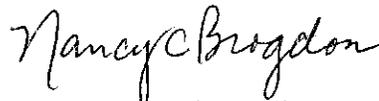
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K070799

Device Name: MODULARIS Variostar

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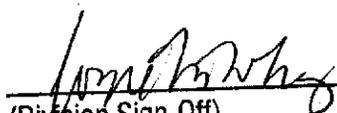
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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 K070799

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