510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the GEMSS UROCAMP Medical Systems Co., Ltd., ASADAL-M1 Extracorporeal Shock Wave Lithotripter.

1. **Company making the submission (Owner):**

Name:	GEMSS UROCAMP
Address:	236-4 Sangdaewon-dong Jungwon-gu Seong nam-si Gyeonggi-do, Korea
Telephone: Fax:	82-31-737-2211 82-31-737-2210
Contact:	Iksoo Kim
E-Mail	kimiksoo@GEMSS UROCAMP.co.kr

2. **Device Name and Classification:**

Trade/Proprietary Name:	Extracorporeal Shock Wave Lithotripter ASADAL-M1
Common/Usual Name:	Extracorporeal Shock Wave Lithotripter
Regulation Number:	876.5990
Product Code:	LNS
Device Class:	II

3. **Predicate Devices:**

Primary Predicate device is the EM-9000 [K101482], Elite Medical Inc., Atlanta, GA. The associate Predicate device is the Lite-Med LM-9200 EOLMA, [K103217], Lite-Med, Inc., and Taipei City, Taiwan.

4. **Indications:**

The GEMSS UROCAMP ASADAL-M1, Extracorporeal Shockwave Lithotripter is indicated for fragmentation of kidney stones such as renal calyx stones and renal pelvic stones and for upper, middle, and lower ureteral stones.

CAUTION: Federal law restricts this device to sale, distribution, and use only upon the lawful order of a physician trained and/or experienced in the use of this device as outlined in an appropriate training program.

Description of Device:

The GEMSS UROCAMP Medical Systems Co., Ltd., ASADAL-M1 is an Electromagnetic Extracorporeal Shock Wave Lithotripter that effectively treats urinary calculi. It is routinely used for the fragmentation of kidney and ureteral stones and offers a good combination of clinical performance, and flexibility. The ASADAL-M1 device consists of a Shockwave Generator, an operator interface panel, and a water circulation subsystem. Shock waves are generated on the basis of a principle similar to that used in loudspeakers. An electrical impulse is sent through an inductance soil, generating a magnetic field which repulses a metallic membrane. The acoustic impulse created by this repulsion is focused by an acoustic lens to form a shock wave. A water circulation subsystem is used to provide transmission of shock waves and cooling of the generator. For the ESWL operation to be fully functional, two or three subsystems are provided. The first is a special treatment table. The second and third are a C-arm X-ray fluoroscope and an ultrasound imaging unit. The treatment table is a motorized floating table which can be moved in all three axes.

5. The Patient Table controls allow movement in the X, Y, and Z plain to adjust the focus of generating shockwave to patients' stones.

6. Patient table

Driving gear	DC 24V Motor
Driving power	Single phase ~220-230VAC, 50/60Hz
Up and down movement	Elevator type
Right and left Movement range	150mm
Front and rear Movement range	150mm
Up and down movement range	300mm
Product size	2120 * 760 * 800
Weight	150kg

7. The control console to include treatment parameter,

Control Type	PLC Controller control type
Power in use	Single phase ~220-230VAC, 50/60Hz
Monitor	Over 22" Wide
PC	Pentium IV
Product size	820 * 715 * 890
Weight	150kg

8. The shockwave generator/shock plug longevity (the number of shocks),

Generating principle	Electro Magnetic Type
Focusing type	Lens focusing type
Input Voltage	0 ~ 220VAC
Output Voltage	0 ~ 20KVDC Step-by-step electric discharge
Control method	Auto / Manual
Discharge cycle	0.6 ~ 10 second (recommend cycle is 1.0 second)
Replacement cycle	1,000,000

9. The water system,

Control Type	IN /OUT Water Pump Type
Water capacity	10Liter
Replacement cycle	3 months

10. The localization/imaging system, and

Controller	EMVIEW
I.I	9" I.I(Thales (TH9428))
TUBE	ROTOR Varian (Rad-99 / OR III)
KV RANGE	40~120KV
MA RANGE	0~5mA, 20mA
Camera	1024 x 1024 Digital Camera Digital Zoom 6", 4.5"
Lens	F 1.2 / 4mm

11. Review of the Technological Characteristics of the device compared to predicate devices:

The ASADAL-M1 and the Primarily Predicate [K101482], and Secondary Predicate [K103217], devices have common Indications for Use, method of construction, method of operation, and design specifications. The technological characteristics of the shock wave are common to all as described in the consensus standard IEC 61846. The results are found similar to the predicate devices characteristics. The ASADAL-M1 device is two separate units, with operator controls in a separate but connected roll around assembly.

12. **Clinical Studies:**

The clinical investigations were performed at two sites with one and two week follow-ups to support this application. The patient population was 142 male and 58 females. None of the patients received general anesthesia.

The experiences of physicians have shown that patients treated by the ASADAL-M1 are safe and without follow-up complications. No incidence of device malfunction appeared in these clinical investigations.

13. Safety Testing:

GEMSS UROCAMP ASADAL-M1, Extracorporeal Shockwave Lithotripter has been tested to the following International Standards with positive outcomes.

Standards №	Standards Title
EN60601-1	Medical electrical equipment Part 1: General requirements for safety
EN60601-1-1	Medical electrical equipment Part 1-1: General requirements for safety-Collateral standard: Safety requirements for medical electrical systems
EN60601-1-2	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance-collateral standard: Electromagnetic compatibility-Requirements and tests
EN60601-1-3	Medical electrical equipment Part 2: particular requirements for the safety of high- voltage generators of diagnostic X-ray generator
EN60601-2-7	Medical electrical equipment Part 2: particular requirements for the safety of high- voltage generators of diagnostic X-ray generator
EN60601-2-28	Medical electrical equipment Part 2: particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
EN60601-2-32	Medical electrical equipment Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
EN60601-2-36	Medical electrical equipment Part 2: particular requirements for the safety of equipment for extra corporeally induced lithotripsy
EN60601-1-4	Medical electrical equipment Part 1-4: General requirements for safety-Collateral standard: Programmable electrical medical systems
EN60601-1-6	Medical electrical equipment Part 1-6: General requirements for safety-Collateral standard: Usability

14. **Rx or OTC:**
The GEMSS UROCAMP ASADAL-M1, Extracorporeal Shockwave Lithotripter is a Rx prescription device per 21 CFR Subpart D.

15. **Conclusions:**

From a clinical perspective and comparing design specifications, the ASADAL-M1 is substantially equivalent to the predicate devices. The ASADAL-M1 meets the FDA requirements stated in *"Guidance for the Content of Premarket Notifications 510(k)s for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi."* GEMSS UROCAMP Medical believes the minor differences of the ASADAL-M1 and its predicate devices should not raise any concerns regarding the overall safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 22, 2014

COMED Medical Systems
% J. Harvey Knauss
Contract Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K131721
Trade/Device Name: Extracorporeal Shock Wave Lithotripter, ASADAL-M1
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Lithotripter, Extracorporeal Shock-Wave, Urological
Regulatory Class: Class II
Product Code: LNS
Dated: June 20, 2014
Received: June 19, 2014

Dear J. Harvey Knauss,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K131721

Device Name

GEMSS UROCAMP ASADAL-M1, Extracorporeal Shockwave Lithotripter

Indications for Use *(Describe)*

The GEMSS UROCAMP ASADAL-M1, Extracorporeal Shockwave Lithotripter is indicated for fragmentation of kidney stones such as renal calyx stones and renal pelvic stones and for upper, middle, and lower ureteral stones.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
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