

K 101482

510(k) SUMMARY

MAR 31 2011

ELITE's EM-9000

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Applicant

ELITE Medical, Inc.

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Contact Person: Steven J. De Brock, President

Prepared Date : 05/06/2010

2. Device Identification

Proprietary Device Name : EM-9000

Common/Generic Device Name : Extracorporeal Shock-wave Lithotripter

Classification Name : Lithotripter, extracorporeal shock-wave, urological

Product Code : LNS

Regulatory Class : Class II

Regulation Number : 21 CFR §876.5990

3. Predicate Devices

The EM-9000 Extracorporeal Shock Wave Lithotripter is substantially equivalent to the following currently marketed devices:

- K040476, Modulith SLX-F2, Karl Storz Endoscopy America Inc.
- K070799, Modularis Variostar, Siemens Medical Solutions, Inc.
- P840008, Compact Sigma, Dornier Medtech America Inc.

4. Description of Device / Technological Characteristics

The EM-9000 consists of: (1) a Therapy Unit; and (2) a Control Interface Master. The Therapy Unit consists of the following sub-modules: (a) shock wave generator with therapy head; (b) patient table (c) optional Ultrasound Localization System ("ULS"); and (d) accessories. The Electronics Module is mounted within the EM-9000's Housing. Since all of the assembly parts are collected on the main body of the unit, it is a self-contained unit for providing the lithotripsy application. The Control Interface Master consists of the following

sub-modules: Hand Held Remote Control Box, Hand Held Table Control Box and Foot Pedal (Optional)

The shock wave generator has a high voltage power supply, a closed circuit water supply system with a tank, an electromagnetic coil, a membrane, an acoustical lens for focusing and a water cushion (rubber membrane) for the acoustic conductivity of the shock waves to the patient. The shock waves are generated by the high voltage discharge through the electromagnetic coil which repels the membrane creating a shockwave. The shockwave is then focused to the focal point. The stones to be fragmented are positioned at this focal point by moving the motorized patient table in 3 axis. The localization is performed with a separate and commercially available mobile fluoroscopic x-ray unit.

5. Intended Use / Indications for Use

The EM-9000 Lithotripsy system is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

6. Performance Data

In accordance with FDA's Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Uretal Calculi (August 9, 2000), ELITE conducted the following types of performance testing: Shock Wave Characteristics; Localization Accuracy; Road Testing; and Clinical Performance Testing. In all instances, the EM-9000 met its specifications and functioned as intended. The laboratory and clinical data provide reasonable assurance of the safety and effectiveness of the EM-9000 for the extracorporeal fragmentation of urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

The shock wave characteristics are reported below in Table-1 by taking the described in the consensus standard IEC 61846 "Ultrasonics - Pressure pulse lithotripters - Characteristics of fields" (1998) into consideration. PVDF film type hydrophones are used in the measurements. The details of the measurements/calculations are given in relevant part of 510(k) application. The results are found similar to the predicate device characteristics.

Pressure at focus is:

EM-9000	Modulith SLX-F2	Modularis variostar	Compact sigma
630 bar	210-1500 (1000) bar	627 bar	510 bar

(see section XII Substantially equivalent chart, for detailed comparison)

Parameter	Min 10 kV	Typical 15 kV	Max 20 kV
Peak-positive acoustic pressure (Mpa)	48	53	62
Peak-negative acoustic pressure (Mpa)	-5.8	-6.6	-7.2
Rise time (ns)	137	128	116
Pressure pulse duration (ns)	511	523	537
Maximum focal width (mm) (x-y plane)	7.6	8.1	7.8
Orthogonal focal width (mm)	8.7	7.9	7.0

Parameter	Min 10 kV	Typical 15 kV	Max 20 kV
Focal extent Fz(mm)	58	68	75
Focal volume (cm ³)	2.00	2.27	2.14
Distance between the focus and target location (mm) (z axis)	3.6	3.6	3.6
Derived focal acoustic pulse energy E ₊ (-6dB) (mJ)	18.3	32.5	32.1

Table-1 Shock Wave Characteristics

Standards

The EM-9000 is designed in accordance with the national and international product safety and performance requirements established in the following standards given in below,

- 1) IEC 60601-1, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance
- 2) IEC 60601-1-1, Medical Electrical Equipment-Part 1 General Requirements for Safety” with Amendment 1 and 2
- 3) IEC 60601-1-2, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance - Collateral Standard : Electromagnetic Compatibility - Requirements and Tests
- 4) IEC 60601-1-4, Medical Electrical Equipment – 1-4: General Requirements for safety – Collateral standard. Programmable electrical systems.
- 5) IEC 60601-2-36, Particular Requirements for safety of equipment for extracorporeally induced lithotripsy
- 6) IEC 60601-2-46, Medical Electrical Equipment, Safety for Operating Table
- 7) IEC 61846, Ultrasonics- Pressure pulse lithotripters - Characteristics of fields (1998)

Results of performance and compliance testing conducted at manufacturing facility and independent test organizations on EM-9000, indicates conformance to all applicable performance standards.

Comparative performance testing demonstrated the EM-9000 to be substantially equivalent to the predicate devices.

7. Clinical Performance Data

The confirmatory clinical study suggests that treatment of urinary tract stones with the EM-9000 is safe and effective.

In accordance with the Lithotripter Guidance, ELITE Medical conducted clinical performance testing in the form of a confirmatory clinical study. A confirmatory clinical study was appropriate because the EM-9000: (1) employs a similar mechanism of action for the generation of shock waves as compared to predicate extracorporeal shock wave lithotripters; and (2) has shock wave characteristics that are within the range of predicate systems.

The clinical data provides reasonable assurance of the safety and effectiveness of the EM-9000 Electromagnetic Lithotripter for the extracorporeal fragmentation of urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

(see section XX Performance Testing – Clinical, for detailed explanations)

8. Conclusion

Based on the comparison to other devices in technological characteristics and intended use, the EM-9000 is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Steven J. De Brock
President
Elite Medical, Inc.
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MARIETTA GA 30062

MAR 31 2011

Re: K101482
Trade/Device Name: EM-9000
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: March 25, 2011
Received: March 28, 2011

Dear Mr. De Brock:

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.

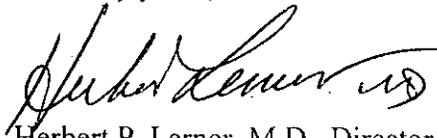
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K101482

Device Name: EM-9000

Indications for Use:

The **EM-9000** Lithotripsy system is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

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 OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K101482

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