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

September 14, 2016

Shockwave Medical, Inc.
Nora Hadding
Vice President, Regulatory Affairs and Quality Assurance
48501 Warm Springs Blvd.,
Suite 108
Fremont, California 94539

Re: K161384
Trade/Device Name: Shockwave Medical Lithoplasty System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PPN
Dated: August 3, 2016
Received: August 4, 2016

Dear Nora Hadding:

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" (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 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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K161384

Device Name
Shockwave Medical Lithoplasty® System

Indications for Use *(Describe)*
The Shockwave Medical Lithoplasty System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92.

**Name, Address, Phone, and Fax Number of Applicant**

Shockwave Medical, Inc.
48501 Warm Springs Blvd., Suite 108
Fremont, CA 94539
Phone: (510) 279-3068
Fax: (510) 279-5934

**Contact Person**

Nora Hadding

**Date Prepared**

May 17, 2016

**Device Name and Classification**

| | |
|---|---|
| **Trade Name:** | Shockwave Medical Lithoplasty® System |
| **Common Name:** | Catheter, angioplasty, peripheral, transluminal |
| **CFR Classification:** | 21 CFR§ 870.1250 |
| **Classification Name:** | Percutaneous catheter |
| **Product Code:** | PPN |

**Predicate Device**

The primary predicate for the Shockwave Medical Lithoplasty System is the Spectranetics, Inc. AngioSculpt PTA Scoring Balloon Catheter (K142983). Additional predicates in terms of intended use and technologic characteristics are the Bard Peripheral Vascular VascuTrak PTA Dilatation Catheter (K103459) and the EKOS Corporation EKOS Lysus Micro-Infusion System (K060422).

**Indications for Use / Intended Use**

The Shockwave Medical Lithoplasty System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

**Device Description**

The Shockwave Medical Lithoplasty System has three components: a proprietary balloon catheter, a generator, and a connector cable. The balloon catheter has integrated lithotripsy emitters and is designed to enhance percutaneous transluminal angioplasty by enabling delivery of the calcium disrupting capability of lithotripsy prior to full balloon dilatation at low pressures. The application of lithotripsy mechanical pulse waves alters the structure of an occlusive

vascular deposit (stenosis) prior to low-pressure balloon dilation of the stenosis and facilitates the passage of blood.

The Lithoplasty Catheter is delivered through the peripheral arterial system of the lower extremities to the site of an otherwise difficult to treat lesion. The balloon is partially inflated and the lithotripsy emitters are energized thereby generating pulsatile mechanical energy within the balloon at the target treatment site and allowing subsequent dilation of a peripheral artery stenosis using low balloon pressure. The Shockwave Medical Lithoplasty Generator delivers energy through the Connector Cable to the pulse emitters located inside the balloon in the Lithoplasty Catheter. The Lithoplasty Catheter is a single-use device supplied sterile to the customer. The Generator and Connector Cable are non-sterile reusable devices.

**Technological Comparison**

The Shockwave Medical Lithoplasty System incorporates substantially equivalent design, dimensional, and performance specifications when compared to the 510(k) cleared AngioSculpt and VascuTrak devices. The Lithoplasty Catheter fundamental scientific technology is the same as the AngioSculpt and VascuTrak devices: sheath and guidewire compatibility, usable catheter length, balloon diameters and lengths, nominal pressure, and rated burst pressure are consistent with the identified predicate devices. The Lithoplasty System also has a similar intended use and indications for use, same target population, and same operating principles as the identified predicate devices.

The Lithoplasty System also has similarities in design and construction as well as principles of operation to the identified predicate EKOS Lysus Micro-Infusion System. Both use catheters that deliver electro-mechanical energy to a blood vessel via a catheter which is connected via a cable to a generator.

**Summary of Performance Data**

Objective evidence demonstrating that the Lithoplasty System design output meets the product design input requirements as well as that device performance characteristics conform to user needs and intended uses as defined in the product specification was provided. Testing was conducted in accordance with Shockwave Medical's Risk Analysis and all applicable FDA guidance documents and relevant international standards. The following tests were conducted for the Lithoplasty Catheter:

- Catheter diameter and balloon profile
- Tensile strength
- Kink resistance / flexibility
- Catheter torsional strength
- Balloon Inflation / deflation time
- Minimum Burst Strength (RBP)
- Balloon compliance
- Fatigue (multiple inflations)
- Pushability and trackability

- Fluoroscopic visibility
- Particulate evaluation
- Pulsing cycles and output

The following tests were conducted for the Lithoplasty Generator and Connector Cable:

- Hardware design verification
- Electrical performance
- Electromagnetic compatibility
- Software verification and validation
- Life expectancy

Results demonstrate that the performance of the Shockwave Medical Lithoplasty Balloon System meets its design specifications and is safe and effective for its intended use.

Summary of Biocompatibility Testing

Biocompatibility testing was not required for the Lithoplasty Generator or Connector Cable because they are non-patient contacting. The Lithoplasty Catheter is categorized as "Externally communicating, Circulating Blood, (A) Limited exposure (<24hrs)". The biocompatibility of the Lithoplasty Catheter was assessed in accordance with ISO 10993-1:2009 – Biological evaluation of medical devices, Part 1 - Evaluation and tests within a risk management process and in accordance with the provisions of 21 CFR 58 Good Laboratory Practices. The following testing was performed: cytotoxicity, sensitization, irritation/intracutaneous reactivity, system toxicity, genotoxicity/mutagenicity, and hemocompatibility. The biocompatibility test results confirm that the Lithoplasty Catheter is non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, non-hemolytic, non-mutagenic and hemocompatible when evaluated under the respective test conditions.

Summary of Animal Testing

A chronic GLP study was conducted in a porcine in vivo model to determine the safety of delivering pulsatile mechanical energy to peripheral arteries with the Lithoplasty System. The histopathology evaluation revealed no trends between the treatment and control groups in injury, inflammation, fibrin, endothelialization or neointimal smooth muscle cells scores. The results demonstrated that the Shockwave Medical Lithoplasty System treatment was overall as safe as the control device in a chronic healthy porcine model.

Summary of Clinical Data

To evaluate the safety and performance of the Lithoplasty System, Shockwave Medical, Inc. conducted a two-phased, non-randomized, multi-center study for the treatment of peripheral stenotic lesions (PAD I and PAD II, combined referred to as the DISRUPT PAD Program). Patients with peripheral arterial disease of Rutherford Category 2, 3, and 4 who were candidates for percutaneous therapy and met the study criteria were enrolled and treated. Thirty-four (34) investigators participated at seven (7) sites in Austria, New Zealand, and Germany. A total of 95 subjects were enrolled. This clinical study summary presents outcomes from all 95 subjects at 30 days and at 6 months.

A total of 95 subjects were enrolled in the study. Baseline characteristics were consistent with a complex, calcified patient population. Calcium burden was significant with severe calcification involving both sides of the arterial wall observed by the Core Lab in 54.7% of the subjects, and an average length of calcium of 93.4 mm. Ninety-four (94) of the 95 subjects received treatment with the Lithoplasty System. The procedures were completed with a low use of adjunctive therapies including pre and post-dilatation balloons and embolic protection filters, along with a low use of stents in this difficult to treat population.

The study met its primary safety endpoint. The lower bound of the 95% confidence interval for freedom from Major Adverse Events (MAE) at 30 days of 97.0% was above the performance goal of 91.3%. The freedom from MAE at 30 days was 100%.

The study also met its primary effectiveness endpoint. The lower bound of the 95% confidence interval for procedural success of 97.0% was above the performance goal of 89.3%. Procedural success was defined as <50% with or without adjunctive therapy was 100%.

The secondary safety endpoint, freedom from MAE at 6 months, continued to be favorable. Freedom from MAE at 6 months was 96.8%. There were no cardiovascular deaths, target limb major amputations, perforations, symptomatic thrombus or distal embolization events.

Secondary effectiveness endpoints were also favorable. Procedural success defined as <50% without adjunctive therapy was achieved in 91.6% of subjects. In addition, procedural success defined as ≤30% with or without adjunctive therapy was achieved in 89.5%. Target lesion patency assessed by duplex ultrasound at 30 days and 6 months was 100% and 76.7% respectively. Three target lesion revascularizations (TLR) occurred within 6 months of follow-up for a true rate of 3.2%.

Functional outcomes including change in ankle-brachial index (ABI), Rutherford Category and walking impairment showed a sustained and statistically significant improvement from baseline and data available at 30 days and 6 months.

In conclusion, the DISRUPT PAD program met the study success criteria. The Lithoplasty System demonstrated safety with minimal vessel injury, and minimal use of stenting. Acute effectiveness results showed high procedural success and a large acute gain in vessel diameter post procedure. Patency, TLR and functional outcomes were durable through 6 months in available patients. These results demonstrate the safety and performance of the Lithoplasty System for the treatment of subjects with calcified, stenotic lesions.

**Basis for Substantial Equivalence**

The Lithoplasty System shares the same intended use, principles of operation, overall technical and functional capabilities, and similar design and materials as the identified predicate devices. Any differences between the Lithoplasty System and predicate devices were evaluated through design verification and validation testing which demonstrated device performance and confirmed that there are no new questions of safety or effectiveness. The Lithoplasty System is therefore substantially equivalent to the predicate devices.