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

December 22, 2016

Shockwave Medical, Inc.
Ms. Plessy Paul
Senior Regulatory Affairs Specialist
48501 Warm Springs Blvd., Suite 108
Fremont, CA 94539

Re: K163306
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: November 22, 2016
Received: November 23, 2016

Dear Ms. Paul:

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,

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)*
K163306

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) 624-9233
Fax: (510) 279-5934

Contact Person

Plessy Paul

Date Prepared

November 22, 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 predicate device is the Shockwave Medical Lithoplasty System, K161384, cleared by FDA on September 14, 2016.

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 proposed Shockwave Medical Lithoplasty System described in this 510(k) Premarket Notification has the same feature set and technological characteristics and is similar tothe predicate device. Updates are being made to the Generator enclosure, display, IV pole mounting mechanism and packaging. In addition, a minor update to dimensions is being made to the Lithoplasty Catheter hub. Lastly, the connectors between the Lithoplasty Catheter, Connector Cable, and Generator are being updated from a mechanical locking to a magnetic electrical connector. The changes are being made to enhance usability and manufacturability.

The proposed device is identical and substantially equivalent to the predicate device Shockwave Medical Lithoplasty System, K161384, in terms of its intended use/ indications for use, as well as fundamental technological characteristics and principles of operation. All technological characteristics of the Shockwave Medical Lithoplasty System are substantially equivalent to the predicate device including scientific technology, design, blood-tissue and patient contacting materials, energy source, shelf life, manufacturing processes, biocompatibility and sterilization.

Summary of Performance Data

Testing of the Lithoplasty Catheter hub update as well as the connections between the Lithoplasty Catheter, Connector Cable, and Generator was performed. To support the Generator enclosure and display updates, hardware, electrical performance, electromagnetic compatibility, and software verification and validation tests were conducted. 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. Component level testing included ISO 594-1:1986 and ISO 594-2: second edition 1998-09-01 testing for the tri-port hub. Generator and Connector Cable safety testing was completed successfully per ANSI/AAMI ES60601-1:2005/(R)2012 and electromagnetic compatibility testing requirements for medical electrical equipment were met per IEC 60601-1-2:2007/A:2010.

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

<u>Summary of Biocompatibility Testing</u>

There have been no changes to the blood tissue or patient contacting components or materials for the Shockwave Medical Lithoplasty System; they are similar to the predicate device. Minor dimensional updates were made to the Triport hub, considered indirect patient contacting, with

no change to the material. Since the component changes were minor, no new biocompatibility testing was warranted.

Sterilization, Shelf life and Packaging
There is no change to the sterilization or shelf life of the Shockwave Medical Lithoplasty System.

Lithoplasty Catheters are individually packaged in a Tyvek/Nylon pouch. There is no change to the packaging of the Shockwave Medical Lithoplasty Catheter requiring additional testing.

The Shockwave Medical Lithoplasty System Generator and Connector Cable are re-usable medical equipment and are provided non-sterile. For ease of user convenience, the packaging of the Lithoplasty Generator, Connector Cable and accessories was updated from Pelican Model 1620 (Pelican Products US) to Pelican Model 1610. Packaging and Simulated Transit testing was completed for the Shockwave Medical Lithoplasty Generator, Connector Cable and accessories packaged in 1610 Pelican case. There is no change to the packaging or packaging materials of the replacement Connector Cable sold separately.

Basis for Substantial Equivalence
The Lithoplasty System shares the same intended use, principles of operation, overall technical and functional capabilities, and similar design and blood tissue contacting materials as the identified predicate device. Any differences between the Lithoplasty System and predicate device 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 device.