June 27, 2018

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

Re: K180454
Trade/Device Name: Shockwave Medical Intravascular Lithotripsy (IVL) System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: PPN
Dated: June 1, 2018
Received: June 4, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eleni Whatley 2018.06.27 15:10:26 -04'00'

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)*
K180454

Device Name
Shockwave Medical Intravascular Lithotripsy (IVL) System

Indications for Use *(Describe)*
The Shockwave Medical Intravascular Lithotripsy (IVL) 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.

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K180454

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) 279-4262
Fax: (510) 279-5934

Contact Person

Plessy Paul
Principal Regulatory Affairs Specialist

Date Prepared

June 1, 2018

Device Name and Classification

Trade Name:	Shockwave Medical Intravascular Lithotripsy (IVL) 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, K163306, cleared by FDA on December 22, 2016.

Indications for Use / Intended Use

The Shockwave Medical Intravascular Lithotripsy (IVL) 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 IVL System has three components: a proprietary balloon Catheter, a Generator, and a Connector Cable. The IVL 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 IVL 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 IVL Generator delivers energy through the IVL Connector Cable to the pulse emitters located inside the balloon in the IVL Catheter. The IVL Catheter is a single-use device supplied sterile to the customer. The IVL Generator and Connector Cable are non-sterile reusable devices.

Technological Comparison

This Traditional 510(k) Premarket Notification is being submitted for a line extension to the Shockwave Medical Inc. Peripheral Intravascular Lithotripsy (IVL) System. An additional four (4) Catheter sizes (2.5mm, 3.0mm, 3.5mm and 4.0mm in diameter and 40mm length) are being added to the existing product offering of 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5 mm and 7.0mm diameter and 60mm length. These additional 4 catheter sizes are referred to as Shockwave S^4 Peripheral Intravascular Lithotripsy (IVL) Catheter. The additional sizes are modifications of the 510(k) cleared Shockwave Medical IVL Catheter design which utilizes lithotripsy and balloon technology to disrupt calcification. The Shockwave S^4 IVL Catheter sizes feature shorter and smaller balloon configurations with smaller crossing profile and the presence of a hydrophilic coating.

The Shockwave S^4 IVL Catheter has the same intended use, principles of operation and has substantially equivalent technological characteristics including same fundamental scientific technology, design, energy source, shelf life, and sterilization as the already 510(k) cleared Shockwave Medical Peripheral IVL Catheter. The Shockwave S^4 IVL Catheter models use the same basic design of the predicate IVL Catheter balloon technology (an IVL catheter with integrated lithotripsy emitters to enable the localized delivery of pulsatile mechanical energy) and utilize lithotripsy to disrupt and restructure calcified lesions to improve tissue flexibility.

Updates were made to the Shockwave S^4 IVL Catheter materials such as balloon material, Inner Lumen Tubing outer layer and colorant as well as adding hydrophilic coating. To accommodate the shorter, smaller balloon configurations with smaller crossing profile updates were made to the numbers of emitters, emitter design and total maximum pulses per catheter. In addition, a minor update to the IVL Catheter Connector was made to reduce system component interdependency. Lastly, the IVL Catheter packaging was updated.

Summary of Performance Data

Objective evidence demonstrating that the Shockwave S^4 IVL Catheter 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 procedures, applicable FDA guidance documents and relevant international standards. Results demonstrate that the performance of the Shockwave S^4 IVL Catheter meets its design specifications and is substantially equivalent to the predicate device.

Performance Testing – Bench

Objective evidence demonstrating that the Shockwave S^4 IVL Catheter 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. The following tests were conducted for the Shockwave S^4 IVL 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
- Temperature Rise
- Guidewire compatibility
- Catheter Sheath Introducer Compatibility
- Catheter Working Length
- Distal Tip Profile
- Distal Tip Durability
- Catheter lubricity
- Coating Length
- Coating uniformity / integrity
- Marker Band Spacing and Alignment
- Emitter Spacing
- Emitter and Marker Band Bond Strength Integrity

The IVL Catheter packaging configuration was evaluated for the impact of product handling, distribution, and the storage environment through to the end-user in accordance with applicable standards.

Bench testing results demonstrate that the Shockwave S^4 IVL Catheter meets its design specifications, and is substantially equivalent to the identified predicate device.

Summary of Biocompatibility Testing

The Shockwave S^4 IVL Catheter is categorized as "Externally communicating, Circulating Blood, (A) Limited exposure (<24hrs)". The biocompatibility of the Shockwave S^4 IVL 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, acute system toxicity, material –mediated pyrogenicity, chemical characterization, and hemocompatibility. The biocompatibility test results confirm that the Shockwave S^4 IVL Catheter is non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, non-hemolytic, and hemocompatible when evaluated under the respective test conditions.

Based on the successful completion of testing, the Shockwave S^4 IVL System meets the product specification and user needs requirements specified in the test protocols and satisfies the design verification testing for dimensions, function, simulated use, system compatibility, and IVL treatment. Testing and results meet the requirements of applicable international standards and FDA guidance documents, demonstrating that the Shockwave S^4 IVL System is substantially equivalent to the identified predicate device.

Clinical Study

The 510(k) submission included the 30 day clinical study results of the DISRUPT BTK Study conducted on a configuration of the predicate Shockwave Medical Peripheral Lithoplasty Catheters in Europe, and included device sizes in 2.5mm, 2.75mm, 3.0mm, 3.25mm and 3.5mm x 60 mm.

The DISRUPT BTK study was a prospective, non-randomized, multi-center 20 patient study including the treatment of stenotic, infrapopliteal arteries with the Shockwave Medical IVL System. A total of twenty subjects were enrolled across three (3) study sites in three (3) countries (Austria, Germany and New Zealand). Baseline characteristics were consistent with a calcified patient population with infrapopliteal lesions. The mean age was 79 years, 40.0% of patients presented with renal insufficiency and the majority of subjects (75.0%) presented with Rutherford Category 5 critical limb ischemia. The mean RVD was 3.2 mm, the mean diameter stenosis 72.6%, and mean lesion length was 52.2 mm.

The IVL Catheter was delivered to the target lesion in 19 subjects (95.0%). In one subject the IVL Catheter could not be delivered, and the procedure was aborted.

The primary safety endpoint, Major Adverse Events (MAE) at 30 days, was 0.0%. There were no deaths, myocardial infarctions, emergency surgical revascularizations or amputations at 30 days post-procedure. No procedure and/or device related adverse events were reported though the 30 day follow-up.

The primary effectiveness endpoint, acute reduction in percent diameter stenosis of target lesion, was 46.5%. Acute effectiveness results showed residual stenosis of 26.2% post-lithotripsy. Vascular complications included one Type B dissection. None of the

subjects experienced a thrombus, abrupt closure, no-reflow, distal embolization or perforation event.

The secondary endpoint was procedural success defined as the ability of the Shockwave Medical IVL System to achieve a post-IVL residual diameter stenosis of ≤50%. All subjects achieved residual diameter stenosis of ≤50%.
The clinical outcomes of this study demonstrated that the Peripheral IVL System can safely and effectively deliver localized pulsatile mechanical energy for balloon dilatation of calcified, stenotic infrapopliteal arteries.

Basis for Substantial Equivalence
The IVL System with the updated Shockwave S^4 IVL Catheter shares the same intended use, principles of operation, overall technical and functional capabilities, and similar design and materials as the identified predicate device. Any differences between the Shockwave S^4 IVL Catheter and predicate catheter were evaluated through design verification and validation testing which demonstrated device performance and confirmed that there are no new questions of safety or effectiveness compared to the predicate device. Based on the nonclinical and clinical tests, the Shockwave S^4 IVL Catheter has been determined to be substantially equivalent to the legally marketed predicate device.