July 26, 2018

Shockwave Medical, Inc.
Ms. Cindy Morrow
Regulatory Affairs Manager
48501 Warm Springs Blvd, Suite 108
Fremont, California 94539

Re: K180958
Trade/Device Name: Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PPN
Dated: June 20, 2018
Received: June 21, 2018

Dear Ms. Cindy Morrow:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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
2018.07.26
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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)*
K180958

Device Name
Shockwave Medical Peripheral Intravascular Lithotripsy System

Indications for Use *(Describe)*
The Shockwave Medical Peripheral 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, infrapopliteal, 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) 279-4262
Fax: (510) 279-5934

Contact Person

Cindy Morrow

Date Prepared

July 25, 2018

Device Name and Classification

Trade Name:	Shockwave Medical Peripheral Intravascular Lithotripsy System
Common Name:	Catheter, lithotripsy, peripheral, transluminal
CFR Classification:	21 CFR 870.1250
Classification Name:	Percutaneous catheter
Product Code:	PPN

Predicate Device

The predicate device is the Shockwave Medical Peripheral Lithoplasty System, K163306, cleared by FDA on December 22, 2016.

Indications for Use / Intended Use

The Shockwave Medical Peripheral 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 Peripheral Intravascular Lithotripsy (IVL) System has three components: a proprietary IVL Catheter, an IVL Generator, and an IVL 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 IVL Catheter. The IVL Catheter is a single-use device supplied sterile to the customer. The IVL Generator and IVL Connector Cable are non-sterile reusable devices.

Technological Comparison

This Traditional 510(k) Premarket Notification is being submitted for software changes to the IVL Generator, including extending the maximum pulse lifetime of the following 60 mm IVL Catheters: 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5 mm and 7.0mm diameter. Minor updates to the IVL Generator were made to the outer enclosure color and battery mounting hardware, the catheter size, pulse count, battery display, and software data table parameters for pulse width from PW0 to PW60. There were changes to the IVL Generator that include count down of the remaining pulse instead of counting up from 0 for each catheter, updates to the software to reduce pixel degradation by employing power saving features, and increasing the maximum useful catheter life from 180 to 300 pulses.

The labeling for all system components has been updated to reflect the new brand name, Intravascular Lithotripsy (IVL).

The IVL System 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 IVL System. The IVL Catheters are the same design as the predicate; the IVL Catheters with integrated lithotripsy emitters enable the localized delivery of pulsatile mechanical energy to disrupt calcified lesions.

Summary of Performance Data

Objective evidence demonstrating that the IVL 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 procedures and all applicable FDA guidance documents and relevant international standards.
Testing included:

- software verification and validation testing of the IVL Generator software
- IVL Catheter design verification and validation testing:
    - Nominal balloon diameter
    - balloon compliance (at 10 ATM)
    - nominal balloon working length measurement
    - emitters and marker band bond strength integrity
    - particulate counts
    - temperature rise assessment

  - sonic output measurement
  - pressure leakage during treatment
  - minimum RBP
  - balloon fatigue (multiple inflations)
  - maximum total pulsing cycles
  - catheter compatibility with specific lithotripsy generator and its accessories designed by Shockwave Medical
- IVL System integration testing
- acoustic field mapping
- in vivo chronic animal testing

Results demonstrated that the performance of the IVL System meets its design specifications and demonstrates substantial equivalence for its intended use; therefore, additional clinical data were not required.

Basis for Substantial Equivalence

The IVL System with modified software 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 IVL Systems 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 IVL System with the updated software is therefore substantially equivalent to the predicate device.