April 25, 2022

Shockwave Medical, Inc.
Soraya Hori
Principal Regulatory Affairs Specialist
5403 Betsy Ross Drive
Santa Clara, California 95054

Re: K221041
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: April 4, 2022
Received: April 8, 2022

Dear Soraya Hori:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221041

Device Name
Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System

Indications for Use *(Describe)*
The Shockwave Medical 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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510(k) Summary - K221041

Name, Address, and Phone Number of Applicant
Shockwave Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, CA 95054
Phone: 1-510-279-4262

Contact Person
Soraya L. Hori

Date Prepared
April 20, 2022

Device Name and Classification

Trade Name:	Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) 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 Intravascular Lithotripsy System, K203365, cleared by FDA on April 22, 2021.

Indications for Use / Intended Use
The Shockwave Medical 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 balloon in 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 Special 510(k) Premarket Notification describes the addition of an alternate energy storage component, software updates consisting of both customer facing features and updates for manufacturability and servicing, and the inclusion of additional data for storage of system event records and the means for non-invasive retrieval of system event records to facilitate enhanced diagnostics and troubleshooting.

The Generator labeling was updated to reference the catalog model number of the modified device, Shockwave 825Dx Generator.

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 510(k) cleared IVL System.

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, applicable FDA guidance documents, and relevant international standards. Testing included:

- Electronic Hardware Design Verification Testing:
    - User interface
    - Battery system
        - Battery charging system
        - Battery management system
    - System power supplies
    - Internal system verification
    - Control system
    - Catheter management system

  - Pulse delivery system
- Software Verification and Validation Testing:
  - Unit Test
  - Integration Test
  - System Test
  - Regression Test
- Extended Life Testing
- 60601-1 Type Testing for Safety and Electromagnetic Compatibility
- Transit Testing

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

Basis for Substantial Equivalence

The IVL System with modified hardware and 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 modified hardware and software is therefore substantially equivalent to the predicate device.