March 22, 2024

Shockwave Medical, Inc.
Anna Bushart
Senior Regulatory Affairs Specialist
5403 Betsy Ross Dr.
Santa Clara, California 95054

Re: K240225
Trade/Device Name: Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave E8 Peripheral IVL Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PPN
Dated: January 26, 2024
Received: January 26, 2024

Dear Anna Bushart:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.03.22 15:15:08 -04'00'

For

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K240225

Device Name

Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave E8 Peripheral IVL Catheter

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, carotid 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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# K240225 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, and Phone Number of Applicant**

Shockwave Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, CA 95054
Phone: (510) 279-4262

**Contact Person**

Anna Bushart

**Date Prepared**

January 26, 2024

**Device Name and Classification**

| | |
|---|---|
| **Trade Name:** | Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave E$^8$ Peripheral IVL Catheter |
| **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, K191840, cleared by FDA on August 7, 2019.

**Reference Device**

The reference 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, carotid or cerebral vasculature.

**Device Description**

The IVL Catheter is a proprietary lithotripsy device delivered through the peripheral arterial system of the lower extremities to the site of an otherwise difficult to treat calcified stenosis. Energizing the lithotripsy device will generate acoustic pressure pulses within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilation of a peripheral artery stenosis using low balloon pressure. The IVL Catheter is comprised of an integrated balloon with an array of integrated lithotripsy emitters for the localized delivery of acoustic pressure pulses. The system consists of an IVL Catheter, an IVL Connector Cable and an IVL Generator.

The Shockwave E$^8$ Peripheral IVL Catheter shaft contains an inflation lumen, a guidewire lumen, and the lithotripsy emitters. The emitters are positioned along the length of the balloon working length for delivery of acoustic pressure pulses. The balloon is located near the distal tip of the catheter. Two radiopaque marker bands within the balloon denote the length of the balloon to aid in positioning of the balloon during treatment. The balloon is designed to provide an expandable segment of known length and diameter at a specific pressure.

The IVL Generator and Connector Cable are used with a Shockwave Medical IVL Catheter to deliver localized, lithotripsy-enhanced, balloon dilatation of calcified, stenotic arteries. The IVL Generator, IVL Connector Cable and IVL Catheters are designed to exchange data during patient treatment.

**Technological Comparison**

This Traditional 510(k) Premarket Notification describes dimensional modifications to the predicate Shockwave S$^4$ Peripheral IVL Catheter and reference Shockwave M$^{5+}$ Peripheral IVL Catheter including increased balloon length, increased catheter length and additional emitter channel.

The catheter labeling was updated to reference the name of the modified device, Shockwave E$^8$ Peripheral IVL Catheter. Additionally, the Shockwave E$^8$ labeling includes a sterile cable sleeve in the packaging to form a convenience kit.

The IVL System has the same intended use, similar 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:

- IVL Catheter design verification and validation testing:
  - Guidewire compatibility
  - Introducer sheath compatibility
  - Nominal balloon diameter
  - Balloon diameter at Rated Burst Pressure (RBP)
  - Balloon length
  - Balloon inflation time
  - Balloon deflation time
  - Useable catheter length
  - Balloon crossing profile
  - Catheter distal tip
  - Distal tip durability
  - Catheter bonds tensile strength
  - Catheter torsional strength
  - Emitter and marker band integrity
  - System leakage
  - Minimum balloon RBP
  - Balloon fatigue (multiple inflations)
  - Sonic output
  - Catheter pulse count and pulse rate
  - Temperature rise
  - Catheter particle count
  - Catheter connector length
  - Catheter connection
  - Catheter identification
  - Catheter sterility (visual inspection)
  - Cable sleeve packaging
  - Catheter compatibility with materials and accessories commonly used in Over-the-Wire (OTW) peripheral balloon angioplasty procedures
  - Simulated use 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 Catheter with dimensional modifications shares the same intended use, similar 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 modified IVL Catheter is therefore substantially equivalent to the predicate device.