



July 27, 2026

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

Re: K262201

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: June 29, 2026

Received: June 29, 2026

Dear Eric Fang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

KRINA M.
PATEL -S

Digitally signed by
KRINA M. PATEL -S
Date: 2026.07.27
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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

Indications for Use

510(k) Number (if known)

K262201

Device Name

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

Indications for Use (Describe)

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, 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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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

Eric Fang

Date Prepared

June 30, 2026

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, K240225, cleared by FDA on March 22, 2024.

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 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, 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 ultrasonic acoustic pressure waves 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 comprises an array of integrated lithotripsy emitters for the localized delivery of ultrasonic acoustic pressure waves and an integrated balloon. The system consists of an IVL Catheter, an IVL Connector Cable and an IVL Generator. The IVL Catheter is available in eight (8) sizes: 2.5 x 80mm, 3.0 x 80mm, 3.5 x 80mm, 4.0 x 80mm, 5.0 x 80mm, 6.0 x 80mm, 7.0 x 80mm, and 8.0 x 80mm. The E8 Peripheral IVL Catheter sizes 2.5x80mm to 6.0x80mm are compatible with a 5-6 F sheath. The E8 Peripheral IVL Catheter sizes 7.0x80mm and 8.0x80mm are compatible with a 7 F sheath. Refer to **Figure 1** below for IVL Catheter components.

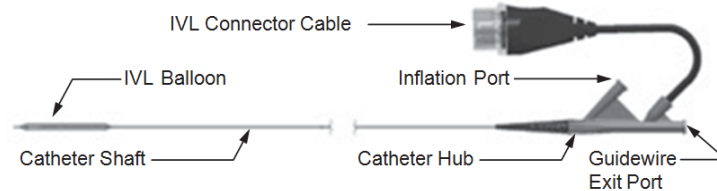


Figure 1: Shockwave E⁸ Peripheral IVL Catheter

The Shockwave E8 Peripheral IVL Catheter shaft contains an inflation lumen, a guidewire lumen, and the lithotripsy emitters. The inflation lumen is used for inflation and deflation of the balloon with 50/50 saline/contrast medium. The guidewire lumen enables the use of a 0.014" guidewire to facilitate advancement of the catheter to and through the target stenosis. The system is designed as 'Over-the-wire' (OTW) with 150cm shaft working length, so an exchange length (300cm) guidewire is indicated. The emitters are positioned along the length of the balloon working length for delivery of ultrasonic acoustic pressure waves. The balloon is located near the distal tip of the catheter and contains a hydrophilic coating designed to increase lubricity during advancement of the catheter to the treatment site. 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 proximal hub has three ports: one for inflation/deflation of the balloon, one for guidewire lumen, and one for connection to the IVL Connector Cable.

Technological Comparison

This Special 510(k) Premarket Notification describes the addition of two additional balloon sizes (7.0x80mm and 8.0x80mm) to the E⁸ Peripheral IVL Catheter family.

The catheter labeling was updated to reference the new finished good device number and the additional size offerings from Shockwave Medical. Additionally, the Shockwave E⁸

labeling includes a sterile cable sleeve in the packaging to form a convenience kit. There is no change to the packaging configuration that was cleared in K240225.

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 demonstrates that the IVL System design output meets the product design input requirements and that device performance characteristics conforming to user needs and intended uses as defined in the product specification were previously provided with K240225. 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
 - Balloon crossing profile
 - Catheter distal tip
 - Distal tip durability
 - Catheter bonds tensile strength
 - Catheter torsional strength
 - System leakage
 - Minimum balloon RBP
 - Balloon fatigue (multiple inflations)
 - Catheter pulse count and pulse rate
 - Catheter particle count
 - 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 is not required.

Basis for Substantial Equivalence

The addition of the 7.0x80mm and 8.0x80mm balloon sizes to the E⁸ Peripheral IVL Catheter shares the same intended use, similar principles of operation, overall technical and functional capabilities, design and materials as the identified predicate device cleared in K240225. Any differences between the IVL Systems were evaluated through design verification and validation testing which demonstrated device performance. The addition of the 7.0x80mm and 8.0x80mm balloon sizes to the E⁸ Peripheral IVL Catheter is therefore substantially equivalent to the predicate device.