September 27, 2024

Shockwave Medical, Inc.
Shira Stone
Senior Regulatory Affairs Specialist
5403 Betsy Ross Drive
Santa Clara, California 95054

Re: K242213
Trade/Device Name: Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral Intravascular Lithotripsy (IVL) Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PPN
Dated: July 26, 2024
Received: July 29, 2024

Dear Shira Stone:

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.

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.09.27 11:42:11 -04'00'

For

Greg O'Connell
Assistant Director
DHT2C: Division of Intervetional
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.

510(k) Number *(if known)*
K242213

Device Name
Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral Intravascular Lithotripsy (IVL) Catheter

Indications for Use *(Describe)*
The Shockwave Medical IVL System with the Javelin Peripheral IVL Catheter is intended for lithotripsy-enabled modification and crossing of calcified lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries, prior to final treatment.
Not for use in the coronary, carotid, cerebral, or pulmonary 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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K242213 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

Shira Stone

Date Prepared

July 26, 2024

Device Name and Classification

Trade Name:	Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral Intravascular Lithotripsy (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.

Indications for Use / Intended Use

The Shockwave Medical IVL System with the Javelin Peripheral IVL Catheter is intended for lithotripsy-enabled modification and crossing of calcified lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries, prior to final treatment.

Not for use in the coronary, carotid, cerebral, or pulmonary 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. Intravascular Lithotripsy (IVL) is an interventional procedure that utilizes a fluid-filled catheter connected to power sources that generate acoustic shock waves; the shock waves modify calcified

plaque in peripheral arteries. Energizing the intravascular lithotripsy device will generate acoustic pressure pulses within the target treatment site, disrupting calcium within the lesion and allowing dilation of peripheral artery stenosis.

The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral Intravascular Lithotripsy (IVL) Catheter consists of three main components: the IVL Catheter, the IVL Generator, and the IVL Connector Cable. The Shockwave Javelin IVL Catheter is comprised of a catheter with an integrated emitter located near the distal end to enable the localized delivery of acoustic pressure pulses in the peripheral vasculature. The emitter is radiopaque to facilitate catheter visibility under fluoroscopy and is surrounded by a fluid-filled space (IVL window) that allows for the transmission of acoustic pressure pulses.

The Shockwave Javelin Peripheral IVL Catheter shaft contains a lumen to pressurize and a lumen to de-pressurize the catheter with saline (the medium to create IVL), a guidewire lumen, and a lithotripsy emitter. The emitter is enclosed within a non-expandable polymer fluid-filled space (i.e., IVL window) containing saline that is connected to the proximal shaft, inlet and outlet ports, and is tapered down to the distal tip of the catheter. The IVL window is located near the distal tip of the catheter. The emitter is radiopaque to facilitate catheter visibility under fluoroscopy and is surrounded by the IVL window that allows for the transmission of acoustic pressure pulses. The IVL window is designed to provide a static catheter profile.

The IVL Generator and Connector Cable are used with the Shockwave Javelin Peripheral IVL Catheter to deliver localized, lithotripsy-enabled modification and crossing 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 including fewer emitters, increased catheter length, distally located emitter, an IVL window in lieu of a balloon, and extended hydrophilic coating length.

The catheter labeling was updated to reference the name of the modified device, Shockwave Javelin Peripheral IVL Catheter, and include clinical study data. The device labeling includes a sterile cable sleeve in the packaging to form a convenience kit.

The IVL System has the same intended use, general purpose, similar principles of operation, and has substantially equivalent technological characteristics including the same fundamental scientific technology, design, energy source, shelf life, and sterilization as the 510(k) cleared Predicate IVL System.

The indication for use statement is similar to the predicate, however minor modifications have been made to further clarify the intended benefit of this specific device which includes modification and crossing of calcified lesions in the peripheral arterial vasculature. The indication

for use reflects both the steps in the instructions for use (IFU) and the recent IDE clinical study results.

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.

- IVL Catheter design verification and validation testing:
  - Guidewire compatibility
  - Introducer sheath compatibility
  - Hydrophilic coating length
  - Hydrophilic coating uniformity
  - Useable catheter length
  - Catheter crossing profile
  - Catheter lubricity
  - Catheter flexibility
  - Catheter kink resistance
  - Catheter distal tip
  - Distal tip durability
  - Catheter bonds tensile strength
  - Catheter torsional strength
  - Emitter band integrity
  - Emitter band alignment
  - Emitter radiopacity
  - Single use design
  - Minimum system burst
  - Catheter fatigue (multiple pressure cycles)
  - 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 and IVL 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.

Summary of Clinical Data

The 510(k) submission included the 30-day pooled clinical study data of the FORWARD PAD IDE Study (FORWARD Study) and New Zealand/Australia Mini-S Feasibility Study (Feasibility Study). Data for the first 90 consecutively enrolled subjects across both studies comprised the pooled analysis cohort. The FORWARD and Feasibility studies were prospective, multi-center, single-arm, studies evaluating the treatment of heavily calcified, stenotic peripheral arteries with the Shockwave Javelin Peripheral Intravascular Lithotripsy (IVL). The subjects in the pooled analysis were enrolled at 19 clinical sites: 15 sites located in the United States, and 4 sites in Australia & New Zealand. Subjects with moderately to severely calcified peripheral artery disease (PAD), Rutherford Category (RC) of 2, 3, 4, or 5 of the target limb, a target lesion located in a native, de novo superficial femoral, popliteal or infrapopliteal artery that met all other study criteria were enrolled and treated. At baseline, the mean age was 74.5 years, and the majority of subjects had a target limb(s) categorized as Rutherford Category 3 (43.3%) or 5 (41.1%). Pre-procedure lesion characteristics, as determined by the Core Lab, showed a mean reference vessel diameter (RVD) of 4.2mm (1.1, 7.4), mean minimum lumen diameter (MLD) of 0.7 mm (0.0, 2.4) with a corresponding mean percentage diameter stenosis of 82.9% (49.9, 100), and mean lesion length of 76.9 mm (8.9, 335.2). Procedural imaging characteristics were collected at pre-procedure, post-Javelin, post-dilatation, and final (end of procedure) timepoints.

The primary safety endpoint for the FORWARD and Feasibility studies was major adverse events (MAEs) at 30 days post-index procedure, defined as a composite of: cardiovascular death; clinically-driven target lesion revascularization (CD-TLR); and unplanned target limb major amputation (above the ankle). All MAEs were adjudicated by an independent Clinical Events Committee. The primary safety endpoint performance goal (PG) for 30-Day MAE rate was 11.2%. The observed 30-day MAE rate was 1.1% (1/90), with an upper 95% confidence limit of 6.0%, which was lower than the Performance Goal of 11.2% ($p=0.0012$). The null hypothesis was rejected, and the 30-Day MAE PG was met.

The primary effectiveness endpoint for the FORWARD PAD and Feasibilities studies was Technical Success, defined as final residual stenosis ≤50% without flow-limiting dissection (≥ Grade D) of the target lesion as assessed by the angiographic core laboratory. The PG for the primary effectiveness endpoint of Technical Success was 85.0%. Technical Success was achieved in 99.0% (97/98) of target lesions with a lower 95% confidence limit of 94.4% which was higher than the PG of 85.0% ($p<0.0001$). The null hypothesis was rejected, and the Technical Success PG was met.

The secondary safety endpoint was serious angiographic complications at the final (end of procedure) timepoint, defined as flow-limiting dissection (≥ Grade D), perforation, distal embolization, or acute vessel closure as assessed by angiographic core lab, which occurred in 1.0% (1/98) of lesions.

Additional secondary endpoints included IVL Technical Success (post-dilatation and final) and IVL Device Success.

- IVL Technical Success, defined as post-dilatation residual stenosis ≤50% without flow-limiting dissection (≥ Grade D) of the target lesion by angiographic core lab (measured immediately following mandatory post-dilatation), was achieved in 89.7% (87/97) of lesions.

- IVL Device Success, defined as the ability to deliver, advance across the target lesion, pressurize, pulse, flush, and retrieve the Javelin IVL catheter, was achieved with 93.0% (107/115) of catheters.

- Technical Success (final), defined as final residual stenosis of ≤30% without flow-limiting dissection (≥ Grade D) of the target lesion by angiographic core lab, was achieved in 78.6% (77/98) of lesions.

Post-Javelin treatment, drug-coated balloons were used in 40.0% (42/105) of lesions and 22.9% (24/105) of the lesions had a stent/Tack implanted. Commercial IVL was used on 25.7% (27/105) of target lesions.

The study collected residual stenosis data post-Javelin, post-dilatation and at the final angiographic time point. Post-Javelin mean residual stenosis was 59.1 ± 18.4% with 36.5% (31/85) of the lesions having a residual stenosis of ≤ 50% and 3.5% (3/85) with a residual stenosis of ≤ 30%. Post-dilatation mean residual stenosis was 31.3 ± 13.7% with 93.8% (91/97) of lesions having residual stenosis of ≤ 50%, and 50.5% (49/97) with a residual stenosis of ≤ 30%. Final mean residual stenosis was 23.0 ± 9.1% with 100% (98/98) of lesions reported with a residual stenosis of ≤ 50%, and with 79.6% (78/98) having a residual stenosis of ≤30%.

The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral Intravascular Lithotripsy (IVL) Catheter demonstrated a low incidence of MAEs and angiographic complications, consistent with prior peripheral IVL studies. Effectiveness results showed acute luminal gain post-Javelin, and low residual stenosis at the final angiographic timepoint.

The clinical outcomes from the analysis demonstrate the substantial equivalence of the Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral IVL Catheter.

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 IVL Catheter is therefore substantially equivalent to the predicate device.