May 2, 2025

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

Re: K243757
Trade/Device Name: Shockwave CS Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 4, 2025
Received: April 4, 2025

Dear Renee Maack:

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,

LYDIA S. GLAW -S
Digitally signed by LYDIA S. GLAW -S
Date: 2025.05.02 17:31:41 -04'00'

Lydia Glaw
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)*
K243757

Device Name
Shockwave CS Guide Catheter

Indications for Use *(Describe)*
The Shockwave CS Guide Catheter is intended to access the coronary venous system and may be used alone (9F) or in a dual catheter delivery (e.g., 9F with 7F). The catheter serves as a conduit for the introduction of interventional/diagnostic devices introduced into the coronary venous system.

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.

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.

I. SUBMITTER

Shockwave Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, CA 95054

Phone: 877-775-4846
Contact Person: Renee Maack
Date Prepared: April 3, 2025

II. DEVICE

Name of Device: Shockwave CS Guide Catheter
Common Name: Guide Catheter
Classification Name: Catheter, percutaneous
Class: II
Product Code: DQY

III. PREDICATE

Boston Scientific Acuity Pro Lead Delivery System (K171612)

IV. DEVICE DESCRIPTION

The Shockwave CS Guide Catheter is a single lumen catheter consisting of a PTFE liner, stainless steel braid, and polymer outer jacket. The transition segments of the catheter have a gradual decrease in stiffness starting from the proximal shaft segment and ending at the distal tip. The Shockwave CS Guide Catheter features a curved distal shaft with radiopaque tip. The proximal end of the guide catheter has a standard luer fitting for connecting to a hemostasis valve. The proximal luer also includes a curve indicator to match the direction of the guide catheter tip curvature and provides a tactile and visual cue to the user. The Shockwave CS Guide Catheter is provided EO sterile and is for single use only.

V. INDICATIONS FOR USE

The Shockwave CS Guide Catheter is intended to access the coronary venous system and may be used alone (9F) or in a dual catheter delivery (e.g., 9F with 7F). The catheter serves as a conduit for the introduction of interventional/diagnostic devices introduced into the coronary venous system.

VI. INDICATIONS FOR USE COMPARISON

Both the subject and predicate device have the same intended use as a conduit for the introduction devices into the coronary venous system. While the Indications for Use statement for the subject device is not identical to the predicate device, the differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate and support substantial equivalence.

VII. TECHNOLOGICAL COMPARISON

The subject and predicate device are percutaneous catheter systems designed to facilitate access and placement of devices within the coronary venous system. A comparison of the intended use and technological characteristics demonstrates that the Shockwave CS Guide Catheter is substantially equivalent to the Boston Scientific Acuity Pro (K171612). The minor differences do not raise new questions for safety and effectiveness.

The Shockwave CS Guide Catheter and Boston Acuity Pro Catheter have the same intended use and sterilization method. They have similar design features such as a radiopaque tip and guidewire compatibility. The Shockwave CS Guide Catheter and Boston Acuity Pro Catheter are equivalent in

terms of principle of operation. There are minor differences in design of the proximal end, as the Shockwave CS Guide Catheter does not have an integrated hub requiring a venous access dilator.

The Shockwave CS Guide Catheter and Cordis Vista Brite Tip (reference device) have the same intended uses and sterilization methods. They have similar design features such as a radiopaque tip and a proximal luer fitting for connecting to a hemostasis valve and are compatible with guidewires. There are minor differences in design of the distal end, as the Shockwave CS Guide Catheter has a pre-curved distal section and the Cordis Vista Brite Tip has a straight distal end.

VIII. SUBSTANTIAL EQUIVALENCE

The following performance testing was performed to demonstrate the device is substantially equivalent to the predicate device, meets its design specification and is as safe and effective as the predicate device.

Biocompatibility

The biocompatibility evaluation of the Shockwave CS Guide Catheter was conducted in accordance with ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. The device is considered an external communicating device with limited (≤24 hour) contact with circulating blood; therefore, evaluation was conducted in the following categories:

- Cytotoxicity
- Hemocompatibility
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Materials-Mediated Pyrogenicity

Design Verification

The following bench testing was conducted to demonstrate that the Shockwave CS Guide Catheter met all performance specifications:

- Visual inspection
- Device dimensions
- Particulate evaluation
- Freedom from Liquid and Air Leakage
- Bond Strength
- Torque Strength
- Flexibility and Kink Resistance
- Corrosion Resistance
- Luer Functionality
- Catheter compatibility
- Radiopacity
- Shelf-life verification

Sterilization

The Shockwave CS Guide Catheter is intended for single use only and is provided sterile via ethylene oxide (EO) gas to achieve a Sterility Assurance Level (SAL) of 10^{-6} per ISO 11135.

Packaging

Packaging verification studies were performed in compliance with the applicable requirements of ISO 11607-1. All device packaging met acceptance criteria following 2X sterilization, environmental conditioning, and transport simulation.

IX. CONCLUSION

Substantial equivalence is demonstrated between the subject device and the predicate device through similar technological characteristics and indications/intended use. There are no differences between the subject device and the predicate that raise new questions for safety and effectiveness. The successful completion of non-clinical testing demonstrates that the Shockwave CS Guide Catheter performs as intended and is substantially equivalent to the predicate.