July 29, 2026

Sonomotion, Inc.
Emily Hergenreter
VP, Clinical Affairs
1600 W. Hillsdale Blvd., Suite 105
San Mateo, California 94402

Re: K262200
Trade/Device Name: Stone Clear (BWSC-LP9-02)
Regulation Number: 21 CFR 876.4690
Regulation Name: Ultrasonic Urinary Stone Propulsion Device
Regulatory Class: II
Product Code: QNA
Dated: June 29, 2026
Received: June 29, 2026

Dear Emily Hergenreter:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262200

Please provide the device trade name(s).

Stone Clear (BWSC-LP9-02)

Please provide your Indications for Use below.

The Stone Clear ultrasonic propulsion device is indicated for the repositioning of residual stone fragments post-lithotripsy that are located in the upper urinary tract of adult patients to facilitate passage, where any individual fragment is less than or equal to 5 mm.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

1. SUBMITTER INFORMATION

Applicant Name:	SonoMotion, Inc.
Applicant Address:	1600 W Hillsdale Blvd Suite 105 San Mateo, CA 94402
Primary Correspondent:	Emily Hergenreter, VP – Clinical Affairs SonoMotion 925-594-9600 emily.hergenreter@sonomotion.com
Secondary Correspondent:	Oren Levy, CEO SonoMotion 415-672-2631 oren.levy@sonomotion.com`
Date Prepared	June 29, 2026

2. DEVICE INFORMATION

Proprietary Trade Name:	Stone Clear™
Common Name:	Ultrasonic urinary stone propulsion device
Classification Name:	Ultrasonic urinary stone propulsion device
Product Code:	QNA
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.4690
Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE

The Stone Clear device is substantially equivalent to the previously cleared Stone Clear ultrasonic urinary stone propulsion device (DEN230082, Product Code: QNA).

4. DEVICE DESCRIPTION

The Stone Clear device is intended for the repositioning of residual stone fragments located in the upper urinary tract of adult patients to facilitate passage, where any individual fragment is less than or equal to 5 mm. The primary components include a diagnostic ultrasound imaging workstation, imaging probes, a high voltage signal generator, and a piezoelectric therapy probe. The generator controls and drives the therapy probe, which delivers the acoustic pulses required for repositioning the stone fragments. A lens is used to focus the acoustic waves to the stone target. The exchange in momentum from the focused

ultrasound beam to the stone fragment(s) causes the fragment(s) to move away from the face of the transducer.

The imaging workstation and associated ultrasound imaging probe provide the user interface and real-time image guidance for the Stone Clear procedure. The imaging and therapy (pushing) probe are coaxially aligned, with the imaging probe docking into the housing of the therapy probe through a capture mechanism (collar). The probe assembly is designed to couple directly to the patient's skin and to be hand-held. A foot pedal is used to initiate the therapy push pulse from the Generator.

The Stone Clear device is a portable system the size of a diagnostic ultrasound system, and the user operates the device similar to a diagnostic ultrasound system. The user applies ultrasound coupling gel to the therapy/imaging probes, places the probe assembly against the patient's skin, and scans the abdomen to locate the stone fragment(s) using standard ultrasound imaging techniques. Once the target fragment(s) is identified, the operator adjusts the probe position so that the fragment(s) is within the target zone, with the direction of pushing force toward the exit of the calyx or kidney. This may be accomplished by adjusting the probe position and/or the patient position. The operator initiates therapy by pressing the foot pedal and monitors the displacement of the fragment(s) in real-time via the coaxial aligned imaging probe. The operator has the option to stop the therapy burst at any time by releasing the foot pedal. If the foot pedal is not released, the Generator will terminate the therapy burst when the maximum duration (e.g., 1 to 3 seconds) is reached.

5. Intended Use/Indications for Use

The Stone Clear ultrasonic propulsion device is indicated for the repositioning of residual stone fragments post-lithotripsy that are located in the upper urinary tract of adult patients to facilitate passage, where any individual fragment is less than or equal to 5 mm.

The Indication for Use for the Stone Clear device is the same as the predicate device.

6. Technological Characteristics Comparison

The SonoMotion Stone Clear device has similar technological characteristics as the predicate device. The differences between the Stone Clear and predicate device do not introduce new or different questions of safety or effectiveness.

Similar Technological Characteristics

The subject Stone Clear device maintains the following similar technological characteristics as the predicate device:

- Non-invasive repositioning of residual stone fragments with focused ultrasound
- Primary system components include a high voltage generator, therapy probe, control console, and imaging/localization system
- Single piezoelectric therapy probe

- Therapy probe couples directly to the skin
- Uses an FDA cleared ultrasound imaging device for imaging/localization system
- Imaging transducer is mounted inline with the therapeutic acoustic wave path
- Probe assembly is handheld
- Transportable for use in multiple healthcare environments

Technological Differences

The Stone Clear device achieves the same function as the predicate device with the following minor technological differences:

- Introduction of RFID technology to support pay-per-use licensing
- Minor system updates (software and user interface) to support pay-per-use licensing
- Coexistence of Stone Clear and Break Wave devices on the same device platform

7. PERFORMANCE DATA

Non-Clinical Performance Data

Applicable safety and performance requirements for medical devices from the following compliance standards were met in support of this premarket notification. Testing is consistent with the predicate device and supports substantial equivalence.

- Electrical Safety and EMC
  - IEC 60601-1
  - IEC 60601-1-2
- Basic Safety and Performance of Medical Electrical Equipment
  - IEC 60601-1
- Acoustic Power and Intensity
  - IEC 60601-2-5
  - IEC 60601-2-36
  - IEC 61846
  - IEC 60601-2-37
- Focal Geometry and Target Accuracy
  - IEC 60601-2-36
  - IEC 61846
- Probe Surface Heating
  - IEC 60601-2-37
- Software Verification and Validation Testing
  - IEC 62304

Additional verification and validation testing was performed to ensure the device met all its design specifications.

8. CONCLUSION

Following the FDA guidance document, ”The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications,“ SonoMotion has established that the Stone Clear (Gen 2.0) device is substantially equivalent to the predicate device. The Stone Clear subject device has the same intended use and many similar characteristics as the predicate device. The non-clinical data provided in support of this premarket notification demonstrate that the minor technological differences between the subject and predicate devices do not raise any new or different questions of safety and effectiveness.