April 29, 2026

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

Re: K261086
Trade/Device Name: Break Wave
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal Shock Wave Lithotripter
Regulatory Class: II
Product Code: LNS
Dated: April 1, 2026
Received: April 1, 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 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,

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

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)*
K261086

Device Name
Break Wave

Indications for Use *(Describe)*
The Break Wave device is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper and lower ureter).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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	March 31, 2026

2. DEVICE INFORMATION

Proprietary Trade Name:	Break Wave™
Common Name:	Extracorporeal Shock Wave Lithotripter
Classification Name:	Lithotripter, Extracorporeal Shock-Wave, Urological
Product Code:	LNS
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.5990
Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE

The Break Wave device is substantially equivalent to the previously cleared Break Wave extracorporeal lithotripter (K252913, Product Code: LNS).

4. DEVICE DESCRIPTION

The Break Wave device is designed for the extracorporeal fragmentation of calculi located in the kidney and ureter. The primary components include a diagnostic ultrasound imaging workstation, imaging probe(s), high voltage signal generator, and piezoelectric acoustic source (therapy probe).

The generator controls and drives the therapy probe, which delivers the acoustic pulses required for breaking stones. A lens is used to focus the acoustic waves onto the target

stone, creating stresses within the stone that result in stone fracture. Repeated application of the acoustic waves breaks the stone into small fragments that can pass spontaneously.

The imaging workstation and associated ultrasound imaging probe provide the user interface and real-time image guidance for the Break Wave procedure. The imaging and therapy probe are coaxially aligned, with the imaging probe docking into the housing of the therapy probe. The probe assembly is designed to couple directly to the patient's skin and be held in place with a mechanical arm or hand-held. Since the therapy probe has a fixed focus, multiple therapy probes are included to target stones over a range of skin-to-stone distances.

The Break Wave device is a portable lithotripter the size of a diagnostic ultrasound system, and the user operates the device similarly to operating 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(s) using standard ultrasound imaging techniques. Once the stone is identified and positioned within the target zone, the operator presses and releases the foot pedal to activate therapy. The operator monitors the fragmentation of the stone in real-time via the coaxial aligned imaging probe. The operator has the option to stop the therapy at any time by pressing and releasing the foot pedal a second time. The procedure will automatically stop at the completion of a single treatment session. The device can be used without the need for patient sedation.

5. Intended Use/Indications for Use

The Break Wave device is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper and lower ureter).

The Indication for Use for the Break Wave device is the same as the predicate device.

6. Technological Characteristics Comparison

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

Similar Technological Characteristics

The subject Break Wave device maintains the following similar technological characteristics as the predicate device:

- Focuses acoustic waves into the body to non-invasively fragment urinary calculi
- Primary system components include a high voltage generator, acoustic wave source, control console, and continuous, in-line ultrasound imaging/localization system
- Multiple piezoelectric therapy probes for targeting stones across a range of depths
- Therapy probes couple directly to the skin

- Therapy probes can be held by hand or with a mechanical arm
- Transportable for use in multiple healthcare environments
- Does not require an integrated system table or water circulation system

Technological Differences

The Break Wave device achieves the same function as the predicate device with the following minor technological differences:

- Decrease in probe diameter for improved acoustic window access and optimization of focal coverage between probes
- Addition of a 4th therapy probe to further optimize the focal coverage between probes
- Introduction of RFID technology for pay-for-use licensing
- Minor updates to the user interface
- Optional components for the mechanical arm accessory
- Optional external display kit that allows the patient to observe the ultrasound image if they are unable to see the primary screen
- Coexistence of Break Wave and Stone Clear devices on the same device platform

7. Performance Data

Non-Clinical Performance Data

The following safety and performance requirements for medical devices and extracorporeal shock wave lithotripsy devices were met in support of this premarket notification. Testing is consistent with the predicate device and supports substantial equivalence.

- Basic Safety and Essential Performance, Electrical Safety, and EMC
  - IEC 60601-1
  - IEC 60601-1-2
- SWL Special Controls
  - IEC 61846
  - IEC 60601-2-36
- Usability
  - IEC 62366
- 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

The Break Wave device meets the FDA requirements stated in "Guidance for the Content of Premarket Notifications 510(k)s for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi" (issued on Aug. 9, 2000) for substantial equivalence. The Break Wave device has the same intended use and many similar characteristics as the predicate device. The non-clinical and clinical data provided in support of this premarket notification demonstrate that the minor technological differences do not raise any new or different questions of safety and effectiveness and the Break Wave device is therefore substantially equivalent to the predicate device.