October 30, 2024

SonoMotion, Inc.
Barbrina Dunmire
Consultant
1600 W. Hillsdale Blvd
Suite 105
San Mateo, California 94402

Re: DEN230082
Trade/Device Name: Stone Clear
Regulation Number: 21 CFR 876.4690
Regulation Name: Ultrasonic urinary stone propulsion device
Regulatory Class: II
Product Code: QNA
Dated: December 6, 2023
Received: December 7, 2023

Dear Barbrina Dunmire:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Stone Clear, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Stone Clear, and substantially equivalent devices of this generic type, into Class II under the generic name ultrasonic urinary stone propulsion device.

The FDA identifies this generic type of device as:

> **Ultrasonic urinary stone propulsion device.** An ultrasonic urinary stone propulsion device visualizes urinary stones in the upper urinary tract and delivers focused acoustic pulses to reposition the stones to facilitate their passage.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may

request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 7, 2023, FDA received your De Novo requesting classification of the Stone Clear. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Stone Clear into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Stone Clear can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

| **Risks to Health** | **Mitigation Measures** |
|---|---|
| Pain or discomfort | Clinical performance data<br>Labeling |
| Damage to underlying tissue from excessive or mistargeted ultrasound application due to mechanical failure, software malfunction, or use error | Non-clinical performance testing<br>Software verification and validation<br>Labeling |
| Thermal injury | Non-clinical performance testing |
| Unsuccessful repositioning | Clinical performance data<br>Labeling |
| Urinary obstruction | Clinical performance data<br>Labeling |
| Hematuria | Clinical performance data<br>Labeling |
| Adverse tissue reaction | Biocompatibility evaluation |
| Infection | Reprocessing validation |
| Electrical shock, burn, or interference | Electrical safety testing<br>Electromagnetic compatibility (EMC) testing |

In combination with the general controls of the FD&C Act, the ultrasonic urinary stone propulsion device is subject to the following special controls:

(1) Clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Data must evaluate the following:
   (i) The device performance in repositioning urinary stones and facilitating their passage; and
   (ii) Device and procedure related adverse events, including pain, discomfort, hematuria, and urinary obstruction.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
  (i) Acoustic output characteristics, including acoustic power and intensity, focal geometry, and target accuracy; and
  (ii) Probe surface heating.
(3) Performance testing must demonstrate the electromagnetic compatibility (EMC), electrical safety, and mechanical safety of the device in the intended use environment.
(4) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.
(5) Performance data must validate the reprocessing instructions for the reusable components of the device.
(6) Software verification, validation, and hazard analysis must be performed.
(7) Labeling must include:
  (i) The size of the stones treated with the device;
  (ii) The acoustic properties of the device;
  (iii) Specific instructions on identifying an appropriate acoustic window;
  (iv) Summary of the clinical performance data conducted with the device; and
  (v) Reprocessing instructions.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the ultrasonic urinary stone propulsion device. they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Esther Kaplan at (301) 796-1863.

Sincerely,

Kellie B. Kelm -S

Kellie B. Kelm, Ph.D.
Acting Office Director
OHT3: Office of Gastrorenal, ObGyn,
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