October 6, 2023

HistoSonics, Inc.
Daniel Kosednar
VP, Regulatory Affairs and Healthcare Compliance Officer
16305 36th Avenue N
Suite 300
Plymouth, Minnesota 55446

Re: DEN220087
Trade/Device Name: Edison System
Regulation Number: 21 CFR 878.4405
Regulation Name: Focused ultrasound system for non-thermal, mechanical tissue ablation
Regulatory Class: Class II
Product Code: QGM
Dated: December 1, 2022
Received: December 2, 2022

Dear Daniel Kosednar:

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 Edison System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Edison System is indicated for the non-invasive destruction of liver tumors, including unresectable liver tumors, using a non-thermal, mechanical process of focused ultrasound.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Edison System, and substantially equivalent devices of this generic type, into Class II under the generic name focused ultrasound system for non-thermal, mechanical tissue ablation.

FDA identifies this generic type of device as:

> **Focused ultrasound system for non-thermal, mechanical tissue ablation**. This device uses focused ultrasound to mechanically ablate soft tissue. The device is not intended to thermally ablate tissue.

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 2, 2022, FDA received your De Novo requesting classification of the Edison System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Edison System 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 Edison System 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**
Impaired tissue or organ function, abscess, pain, or other adverse events downstream of tissue ablation	Clinical performance testing Labeling Human factors Testing
Acoustic path, non-targeted tissue injury	Clinical performance testing Human factors Testing Animal performance testing Non-clinical performance testing
Tissue injury due to device malfunction or misuse	Clinical performance testing Software verification, validation and hazard analysis Non-clinical performance testing Labeling Human factors Testing
Adverse tissue reaction	Biocompatibility evaluation
Electrical shock or electromagnetic interference	Electrical safety testing Electromagnetic compatibility testing Labeling

In combination with the general controls of the FD&C Act, the focused ultrasound system for non-thermal, mechanical tissue ablation is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must document the adverse event profile and characterize tissue destruction.
(2) Animal performance testing must demonstrate that the device mechanically destroys targeted tissue while characterizing the chronic safety profile, including thermal and mechanical injury to adjacent, non-target tissue.

(3) 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 characterization at clinically relevant settings;
   (ii) Determination of the minimum drive voltages necessary to sustain a bubble cloud in the target tissue;
   (iii) Validation of mechanisms to prevent energy delivery that would result in adverse thermal effects;
   (iv) Availability of real-time monitoring during the procedure;
   (v) Validation that the treatment zone is limited to the defined target tissue; and
   (vi) Validation of mechanisms to prevent, pause and terminate ablation in the event of device failure.
(4) Performance data must support the electrical safety and electromagnetic compatibility of the device.
(5) All patient-contacting components of the device must be demonstrated to be biocompatible.
(6) Software validation, verification, and hazard analysis must be performed.
(7) Human factors testing must demonstrate that the user can safely and correctly use the device.
(8) Labeling must include the following:
   (i) A warning that focused ultrasound ablation should only be considered in patients with sufficient functional reserve to withstand the destruction of the planned volume of tissue;
   (ii) A statement that the device has not been evaluated for the treatment of any specific disease or condition; and
   (iii) A detailed summary of the clinical testing with the device.

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 focused ultrasound system for non-thermal, mechanical tissue ablation 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 Cal Rabang, Ph.D. at 301-796-6412.

Sincerely,

Binita S. Ashar -S

FDA

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Director
OHT4: Office of Surgical
and Infection Control Devices
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