



March 13, 2024

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

Re: K233466

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: February 14, 2024  
Received: February 14, 2024

Dear Daniel Kosednar:

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.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark  
Trumbore -S

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Date: 2024.03.13  
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Mark Trumbore, Ph.D.

Assistant Director

DHT4A: Division of General Surgery Devices

OHT4: Office of Surgical

and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K233466

Device Name

Edison System

Indications for Use (Describe)

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.

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.

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## 510(k) Summary

HistoSonics, Inc.  
Traditional 510(k)  
Edison® System

### 1. Submitter

#### 510(k) Submitter:

HistoSonics, Inc.  
16305 36<sup>th</sup> Avenue N, Suite 300  
Plymouth, MN 55446 U.S.A.

#### Contact Person:

Dan Kosednar  
VP of Regulatory Affairs  
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**Date Prepared: 13 March 2024**

### 2. Subject Device

Trade Name: Edison® System  
Classification Name: Focused ultrasound system for non-thermal, mechanical tissue ablation  
Regulation Number: 21 CFR Part 878.4405  
Product code: QGM

### 3. Predicate Device

Device Name: Edison System  
De Novo: DEN220087  
Classification Name: Focused ultrasound system for non-thermal, mechanical tissue ablation  
Regulation Number: 21 CFR Part 878.4405  
Product code: QGM

### 4. 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.

### 5. Device Description

The HistoSonics Edison System (the “System”) provides users with a means to identify, target and destroy liver tumors entirely non-invasively using histotripsy, a non-ionizing, non-

thermal, mechanical process of focused ultrasound. Histotripsy is created by delivering high amplitude, very short (microsecond), focused ultrasound pulses designed to induce controlled acoustic cavitation at a known focal location in the form of a "bubble cloud". The bubble cloud is a cluster of microbubbles that form, rapidly expand and collapse, imparting significant stress and strain on soft tissue, including liver tissue. After an adequate number of pulses (less than a few seconds at each bubble cloud location), liver tissue within the bubble cloud is mechanically destroyed, resulting in an acellular lysate with limited to no recognizable cellular structures. Acoustic cavitation (and bubble cloud formation) is only created when there is sufficient negative pressure to exceed the cavitation threshold, making it a threshold phenomenon.

The System is comprised of reusable medical equipment and disposable, single-patient use components intended for use in a professional healthcare environment. Reusable portions of the system include the Treatment Cart and a Support Arm and frame that is used to contain ultrasound medium (degassed water) that acoustically couples the system to the patient. Disposable aspects of the system include a clear, acoustically transparent and deformable membrane that holds the ultrasound medium as well as various non-active accessories used during patient set up. The Treatment Cart includes a Treatment Arm/Micropositioning System which is comprised of a six degree of freedom (6 DOF), dual encoded robotic arm. At the end of the arm is the Treatment Head which contains the histotripsy therapy transducer and a coaxially aligned diagnostic ultrasound probe. System software controls the Treatment Arm to direct the bubble cloud through the planned treatment volume.

The System is functionally integrated with a GE LOGIQ E10s ultrasound system (K211524), which is provided by HistoSonics with each Edison System.

## **6. Summary of Characteristics Compared to Predicate Devices**

The Edison System under review is substantially equivalent to the Edison System cleared under DEN220087. The Edison System has the same technological characteristics as the predicates, that is, they operate in the same manner through the non-thermal, mechanical destruction of liver tumors by using non-invasive focused ultrasound.

Overall, the subject and primary predicate devices are all based on the same technological aspects as follows:

- no change to the core histotripsy parameters or dose
- no increase in the level or amount of focused ultrasound energy delivered
- same thermal cooling table applied

The following primary technological differences exist between the subject and predicate devices:

- Larger bubble cloud size of ~3x3x11mm (subject device) versus a ~3x3x6mm (predicate device) via the use of dynamic electronic micro-steering.
- 3cm diameter sphere treated with the predicate device would take a minimum of 23 minutes while the subject device will take a minimum of approximately 13 minutes.

See table below for a detailed summary of the characteristics compared to the predicate device.

<b>Characteristic</b>	<b>Edison System (Predicate Device) DEN220087</b>	<b>Edison System (Subject Device)</b>
Product Name	Edison System	Same
Device Classification	Class II	Same
FDA Product Code	QGM	Same
Indication 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.	Same
Anatomical Site	Liver	Same
Use Environment	Professional Healthcare Environment	Same
Software Version	2.0.1	2.1.2
Integrated Diagnostic Ultrasound System	GE LOGIQ E10s (K211524)	Same
<b>Treatment Cart</b>		
Generator	64-channel amplifier	64-channel amplifier updated for manufacturability, no functional changes
High Voltage Power Supply	5 amp max current (3.5 amp average draw) power supply	10 amp max current (3.5 amp average draw) power supply
Power Distribution Box	1U Rackmount, 12V power supply	2U Rackmount. 12V power supply
Uninterruptable Power Supply (UPS)	Not applicable	1U Rackmount, 770 Watt output with 120VAC input

Characteristic	Edison System (Predicate Device) DEN220087	Edison System (Subject Device)
<b>Required Workflow</b>		
System Setup	Required steps include Log-in, Position Treatment Arm, Attach/Select Treatment Head, Position Imaging Probe, Submerge Treatment Head, Calibrate Crosshairs, and Patient Registration	Same
Patient Preparation (Localize)	Required steps include Patient Preparation, Patient Coupling, Wheel Lock and Calibrate Resistance Detection	Same
Plan	Required steps include Position Contours, Verify Set-up by surveying the plan to assure that the resistance is acceptable, Mark Muscle Layer and Verify Plan	Same
Treat	Required steps include Calibrate Crosshairs In Vivo, Establish Voltage Settings and Automated Treatment	Same
System Shutdown	Required steps include Remove Treatment Head and Move Treatment Arm to Storage position	Same
<b>Optional Workflow</b>		
DICOM Image Viewer	IMFusion Software v2.45.15	Same
Image Fusion Workflow	Workflow steps include Breath Hold and Image Sweep, Review/Trim recording, Establish Registration Points, Fuse and Review/Accept Results	Same

Characteristic	Edison System (Predicate Device) DEN220087	Edison System (Subject Device)
<b>Treatment Head</b>		
Treatment Heads Available	2 – 52 element and 56 element	Same
Integrated Diagnostic Ultrasound Imaging Probe	GE C1-6-D	GE C1-6VN-D
Imaging Probe Rotation	+/- 180 degrees in X/Y	Same
Imaging Probe Translation	+ 5cm translation in Z	Same
Imaging Probe Mounting	Coaxial	Same
Imaging refresh rate	Continuous, Live stream	Same
<b>Histotripsy Therapy Parameters</b>		
Bubble Cloud Size	~3x3x6mm	~3x3x11mm
Treatment plan size range	<ul style="list-style-type: none"> <li>• no more than a 2:1 ratio from largest to smallest diameter</li> <li>• no less than 15 mm in any diameter (X, Y, Z)</li> <li>• no more than 40 mm in any diameter (X, Y, Z)</li> </ul>	<ul style="list-style-type: none"> <li>• no more than a 1.5:1 ratio from largest to smallest diameter</li> <li>• no less than 20 mm in any diameter (X, Y, Z)</li> <li>• no more than 40 mm in any diameter (X, Y, Z)</li> </ul>
Focal Steering – Static Focus	Static Focal Steering to achieve 1 cm to 2 cm extended depth from natural focus	Same
Focal Steering – Dynamic Micro-steering	Feature available but not incorporated	Automated Focal micro-steering to achieve larger bubble cloud
Thermal Profile	Thermally-safe treatment protocol embedded in software.	Same
Minimum treatment time for 3cm Diameter Sphere	~23 min	~13 min

Characteristic	Edison System (Predicate Device) DEN220087	Edison System (Subject Device)
<b>Accessories / Patient Coupling Solution</b>		
Support Arm with attached bedrail clamp and upper/lower frame	3DOF, multi-joint arm 1" bedrail clamp Molded Frame components	Same
Patient membrane	Proprietary Styrene-ethylene-butylene-styrene (SEBS) membrane overmolded on molded polypropylene frame	Same
Patient/Membrane Coupling Oil	Castor Oil	Same
Membrane Cradle	Silicone web	Same
Bubble Evacuation Tool	Off the shelf catheter and syringe	Custom molded bulb and tube design
Inspection Mirror	Included	Same
Ultrasound Coupling Media	Degassed Water	Same

The bench and in-vivo animal study conducted demonstrate that the minor technological differences do not raise any different questions of safety and effectiveness and the subject device is as safe and effective as the predicate devices. In conclusion, the Edison System under review is substantially equivalent to the predicate device.

## 7. Performance Data

In accordance with the required device Special Controls, non-clinical performance testing was performed on the modified Edison System which demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance documents. The following performance data was provided in support of the substantial equivalence determination.

### Design Verification and Validation Testing Data:

Design verification and validation testing was conducted and demonstrated that the Edison System meets defined product specification and its intended use. The design verification and validation testing included:

- Acoustic Characterization in accordance with IEC 60601-2-62:2013 *Medical electrical equipment- Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment.*

- Software Testing in accordance with ISO 62304:2015 *Medical device software – Software life cycle processes*.
- System and Subsystem Verification Testing

**Cybersecurity Compliance Information:**

Information demonstrating compliance with section 525B of the FD&C Action per current “FDA Guidance: Cybersecurity in Medical Devices - Quality System Considerations and Content of Premarket Submissions” was provided in this submission.

**Animal Study Data:**

A GLP compliant preclinical study was conducted in a porcine model undergoing histotripsy procedure utilizing the predicate and modified Edison System. All acceptance criteria were met. Therefore, the design of the modified Edison System meets the intended use. The results from the testing demonstrate that the subject device does not raise any different questions of safety and effectiveness.

**Additional Considerations Specific to Special Controls:**

Changes to the subject device did not require further testing in support of IEC 60601-1:2020 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* or IEC 60601-1-2:2020 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests*.

There have been no device changes that impacted the critical tasks associated with the modified Edison System and therefore the previously conducted usability testing in accordance with ISO 62366-1:2020 *Medical devices – Part 1: Application of usability engineering to medical devices* is still applicable.

Finally, there have no changes to the patient contacting accessories that would impact the devices compliance with the following standards:

- ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing*;
- ISO 10993-5:2009 *Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity*;
- ISO 10993-10:2021 *Biological evaluation of medical devices -- Part 10: Tests for skin sensitization*;
- ISO 10993-23:2021 *Biological evaluation of medical devices -- Part 23: Tests for irritation*; and

- FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* September 8, 2023.

## **8. Substantial Equivalence Discussion**

The Edison System under review has the same intended use, indications for use, anatomical site, principle of operation, and technological characteristics as the predicate device identified in this submission.

Furthermore, the design verification and validation testing performed demonstrate the subject device meets defined product specification and intended use. In addition, the bench and GLP animal comparison testing with the predicate device demonstrate that the subject device has comparable performance to the predicate device and the minor technological characteristics differences do not raise any different questions of safety and effectiveness.

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the Edison System has been shown to be substantially equivalent to the predicate device identified in this submission.