May 29, 2026

HistoSonics, Inc.
LeeAnne Swiridow
Director, Regulatory Affairs
16305 36th Avenue N
Suite 300
Plymouth, Minnesota 55446

Re: K252947
Trade/Device Name: HistoSonics® Planning Tool
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QTZ
Dated: April 25, 2026
Received: April 27, 2026

Dear LeeAnne Swiridow:

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 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,

for

Jessica Lamb, Ph.D
Assistant Director, Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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.	K252947

Please provide the device trade name(s).

HistoSonics® Planning Tool

Please provide your Indications for Use below.

The HistoSonics Planning Tool is a stand-alone software product that allows physicians to visualize and compare CT and MRI imaging data. The display, annotation, and volume rendering of medical images aids in histotripsy procedures conducted using HistoSonics Histotripsy Systems. The software is not intended for diagnosis. The software is used to evaluate images in the region of interest for patients deemed suitable for histotripsy by the treating physician.

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

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

HISTOSONICS®

510(k) Summary

HistoSonics, Inc.

Traditional 510(k)

HistoSonics® Planning Tool

1. Submitter

510(k) Submitter:

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

Contact Person:

LeeAnne Swiridow
Director of Regulatory Affairs
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Email: leeanne.swiridow@histosonics.com

Date Prepared: 27 May 2026

2. Subject Device

Trade Name:	HistoSonics® Planning Tool
Regulation Number:	21 CFR Part 892.2050
Regulation Description:	Medical image management and processing system
Product code:	QTZ
Classification Name:	System, Image Processing, Radiological
Regulatory Class:	II
Special Controls:	Compliance with Voluntary Standards: (1) Digital Imaging and Communications in Medicine (DICOM) Standard

3. Predicate Device

Device Name:	Emprint Visualization System
510(k):	K192038
Device Common Name:	DICOM Viewer
Regulation Number:	21 CFR Part 892.2050
Regulatory Description:	Medical image management and processing system
Product code:	LLZ
Classification Name:	System, Image Processing, Radiological
Manufacturer:	Covidien llc

4. Indications for Use

The HistoSonics Planning Tool is a stand-alone software product that allows physicians to visualize and compare CT and MRI imaging data. The display, annotation, and volume rendering of medical images aids in histotripsy procedures conducted using HistoSonics Histotripsy Systems. The software is not intended for diagnosis. The software is used to evaluate images in the region of interest for patients deemed suitable for histotripsy by the treating physician.

5. Device Description

The HistoSonics Planning Tool is a specialized software application that assists physicians in planning histotripsy procedures to be completed using the HistoSonics Edison® System (histotripsy system, K241902). The HistoSonics Planning Tool imports and displays MR or CT studies and allows the user to simulate the patient's position (orientation) for the procedure, along with the placement of the treatment head and reservoir. Physicians use the HistoSonics Planning Tool to localize the target, define the planned treatment volume, and determine the optimal acoustic pathway within the physical constraints of the setup. The HistoSonics Planning Tool and the histotripsy system do not interact or share data.

The HistoSonics Planning Tool overlays simulated treatment planning elements onto the imported imaging studies, allowing physicians to check whether the target is within the treatment range of the system and whether there is excessive blockage within the acoustic field that would prevent treatment.

The HistoSonics Planning Tool also helps assess setup feasibility by identifying potential limitations, such as when the physical space required for the treatment head, reservoir, and patient positioning would result in unavoidable collisions or prevent the system from being configured as required to reach the target.

Using the HistoSonics Planning Tool enables the treating physician to assess patient positioning, treatment head selection, acoustic pathway and help assess whether a tumor is viable for histotripsy treatment in advance of the histotripsy procedure. Compared to histotripsy procedures where the HistoSonics Planning Tool is not used, utilizing the HistoSonics Planning Tool to determine these key aspects of the procedure workflow in advance of the patient being treated has the potential to reduce the overall time the patient is in the procedure room/under anesthetic.

6. Summary of Characteristics Compared to Predicate Devices

The HistoSonics Planning Tool is a stand-along software product (SaMD), DICOM (Digital Imaging and Communications in Medicine) image viewer which incorporates histotripsy related overlays for procedure planning purposes. It can be installed either on a Windows based laptop computer or accessed through a secure cloud-based platform. Like the predicate, the HistoSonics Planning Tool is an image processing tool that aids in procedure planning for a focal therapy device. It relies on the same principle of operation and fundamental technology and has similar performance characteristics as the predicate device, which differ only due to the underlaying technology (histotripsy vs microwave ablation).

As with the predicate (and as it relates to the related Emprint™ Ablation System), the HistoSonics Planning Tool imports DICOM data from CT and MR scanners and can display the images in standard axial, coronal, or sagittal views and render the images in 3-D views. The HistoSonics Planning Tool principles of operation allows the user to import multiple DICOM compatible CT and MR image sets, render them into 3-D and compare them. The software also provides tools to mark and measure anatomical features and to overlay the anticipated histotripsy acoustic pathway as defined by the HistoSonics Edison® System (K241902).

The primary technological difference between the subject and predicate devices is the ability of the subject device to allow for automatic segmentation of key organs as selected by the user. This feature is designed to allow for visualization of key structures which may be in the acoustic pathway.

Characteristic	**Emprint Visualization Application (Predicate Device)** K192038	**HistoSonics Planning Tool (Subject Device)**
Product Name	Emprint™ Visualization Application	HistoSonics® Planning Tool
Device Classification	Class II	Same
FDA Product Code	LLZ (21 CFR Part 892.2050)	QTZ (21 CFR Part 892.2050)

Characteristic	Emprint Visualization Application (Predicate Device) K192038	HistoSonics Planning Tool (Subject Device)
Indication for Use	The Emprint™ Visualization Application is a stand-alone software product that allows physicians to visualize and compare CT and MRI imaging data. The display, annotation, and volume rendering of medical images aids in ablation procedures conducted using Emprint™ ablation systems. The software is not intended for diagnosis.	Similar – The indications for use reflect the therapeutic device for which the subject device serves as a planning aid. The HistoSonics Planning Tool is a stand-alone software product that allows physicians to visualize and compare CT and MRI imaging data. The display, annotation, and volume rendering of medical images aids in histotripsy procedures conducted using HistoSonics Histotripsy Systems. The software is not intended for diagnosis. The software is used to evaluate images in the region of interest for patients deemed suitable for histotripsy by the treating physician.
Use Environment	Professional Healthcare Environment - Local Laptop application	Similar. The HistoSonics Planning Tool operates in a professional healthcare environment and allows for a local laptop installation or use in a cloud-based environment.
Software Version	2.0	1.0 – This is the initial release of the HistoSonics Planning Tool.
Software Features		
Import DICOM	Allowed	Same
Select anatomical features	Allowed	Same
Measure and Mark anatomical features, including annotation	Allowed	Same
Overlay and position virtual device images	Included	Same
Compare imported images simultaneously	2 images can be compared	At least 3 series can be compared
Export of plans to patient record	Allowed	Not incorporated

The minor technological differences between the subject and predicate device 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 HistoSonics Planning Tool under review is substantially equivalent to the predicate device.

7. Performance Data

Extensive software testing was conducted for the SaMD product and included both software subsystem verification and system-level validation. Subsystem testing included unit and integration testing, while system-level validation was conducted to fully evaluate the performance of the application's user interface.

Performance testing demonstrated the HistoSonics Planning Tool's compliance with the following international standards:

1)International Standard IEC 62304:2015, Medical Device Software – Software Life Cycle Processes

2) NEMA PS 3.1-3.20:2024e, Digital Imaging and COmmunications in Medicine (DICOM)

7.1. Machine Learning Segmentation Model

7.1.1. Model Description

The HistoSonics Planning Tool includes algorithms to segment the liver, kidney, lungs, ribs, and skin in MRI and CT images to provide insights used for planning histotripsy procedures including patient setup and planning simulation. All of the segmentation models, except skin, were developed using machine-learning. The models are static when implemented into the HistoSonics Planning Tool; the device does not incorporate adaptive machine-learning.

7.1.2. Specifications of the Training Dataset

The overall training dataset was sourced from six publicly available datasets and one proprietary dataset representing over 30 institutions across the United States, Europe and China. Based on the available data, the six public datasets comprised a combined total of over 3000 scans, with an approximate 6:1 CT to MR ratio. Imaging was performed across more than 22 scanner models from Philips, Siemens, GE, and Toshiba/Canon. Scan parameters included 1.5T and 3.0T field strengths for MR acquisitions and 120 kVp tube voltage for CT acquisitions and contrast utilization varied by dataset. Patient age across the combined datasets ranged from 14 to 100 years and gender was approximately a 2:1 male to female ratio, when reported. The datasets included patients with oncological disease, patients undergoing routine cancer screening, healthy subjects, and patients with unknown pathology status.

7.1.3. Validation Data Description

The dataset for evaluation was compiled from two publicly available datasets, CRLM and CirrMRI600+, and a proprietary dataset owned by HistoSonics. In the selection of data taken from each dataset, a balance between sex and modalities was applied, and all age groups are represented. The z-spacing of the volumes was required to be at least 3mm or better. This dataset is independent of the training data and was not used to develop the Planning Tool's segmentation algorithms. The datasets are summarized below.

The CLRM dataset includes a total 197 patients, with a mean age of 61 years (ranging from 30 to 88), and a gender distribution of 117 males and 59 females. For the purposes of model evaluation, a selected subset of 10 patients was used, evenly split between males and females (5 each), with a mean age of 56 years (range: 33–85). The data was collected from one facility from 1991 to 1995 and the Lightspeed 16 and VCT models from GE Healthcare were utilized. Clinically, 58% of the total dataset had multiple metastases, with maximal tumor size averaging 3.5 cm (±2.6 cm). The median percentage of necrosis was 30% (ranging from 0 to 90%), and the median percentage of fibrosis was 10% (ranging from 0 to 100%).

The CirrMRI600+ dataset comprises 339 patients, with a mean age of 60 years (range: 20–92), and a gender distribution of 204 males and 133 females. For the purposes of model evaluation, 10 patients were selected, balanced between genders (5 male, 5 female), with a mean age of 53 years (range: 24–80). Imaging was performed at one Turkish site using Philips (1.5T and 3T) and Siemens (1.5T) scanners. The overall dataset includes both healthy subjects and those with cirrhosis, covering a spectrum from mild fibrosis to advanced disease. T1-weighted images were acquired using gradient echo techniques, mostly in the post-contrast portal venous phase.

The proprietary HistoSonics Dataset includes a total patient population of 55 patients, ages 36-81 (Mean 61) with a mix of HCC tumors and liver metastasis and includes patients who were not ultimately enrolled in the #HOPE4LIVER study. Sex distribution is unknown, but was 50/50 in the study. The data acquisition occurred at 10 sites in the US and Europe using various MR and CT scanners (Imaging parameters: MR - T1w or T2w, with slice thickness <= 3mm; CT-soft tissue window, with slice thickness <= 3mm). Data was collected between April 2021 and January 2023.

7.1.4. Ground Truth

A consensus ground truth is established through manual segmentation of CT and MRI scans from 78 scans. Three sets of independent annotations were performed by trained annotators and overseen by radiologists. The three sets of annotations were merged

with the STAPLE algorithm (Warfield et al. 2004) into one ground truth annotation, against which the evaluations were performed.

7.1.5. Statistical Analysis

Ground Truth Validation: Using the Dice coefficient is validated through comparison with segmentations from three annotators. Statistical analysis indicated no significant discrepancies between these individual segmentations and the consensus ground truth, thereby substantiating the consistency of the annotations and the reliability of the ground truth. Each segmentation model in this category (Liver, Kidney and Lung) exceeded the acceptance criteria of dice score 70% or higher in 70% of the cases (Mean 93%, 89% and 92% respectively).

Geometric comparison of Planning Tool with Ground Truth: An evaluation of Planning Tool's automated segmentations were conducted by comparing them to the ground truth, utilizing Dice scores as quantitative measures. The algorithm's performance met the established criteria. The Rib segmentation model exceeded the acceptance criteria of being within 5mm of the inter-annotator average surface distance (Mean 92%).

7.1.6. Subgroup Error Analysis:

Subgroup analyses were conducted across variations such as age (24-85), gender (M/F, 50/50) and geographic regions (US and Europe), as well as imaging modality (CT vs MR, 2:1 ratio). The Planning Tool met the criteria for both correlation and relative volume difference across all subgroups with no statistically relevant differences, demonstrating robustness and generalizability of the model.

7.2. Conclusions:

The evaluation provides objective evidence supporting the reliability, accuracy, and reproducibility of the HistoSonics Planning Tool for automated segmentation. Validation and performance testing demonstrate that the device meets predefined acceptance criteria for its intended use in clinical workflows. The results support the device's suitability for use by qualified healthcare professionals in the assessment of histotripsy planning. Furthermore, the HistoSonics Planning Tool has been demonstrated to be substantially equivalent to its predicate device, Emprint Visualization System (K192038), with respect to intended use, technological characteristics, and performance.

7.3. Pre-clinical/Clinical Study Data:

No safety related risks were identified as a result of the use of the HistoSonics Planning Tool. The device performance was validated through system level software testing and therefore, animal studies and clinical studies in human subjects were not required.

7.4. 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.

8. Substantial Equivalence Discussion

The HistoSonics Planning Tool under review has the same intended use, indications for use, principle of operation, and technological characteristics as the predicate device identified in this submission.

Furthermore, the design verification and validation testing performed, as well as compliance with the NEMA DICOM Standard (PS 3.1 - 3.20 2024e), demonstrates the subject device meets defined product specification and intended use. In addition, the minor technological characteristic differences do not raise any different questions of substantial equivalence.

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