September 4, 2024

Sonic Incytes
% Rhona Shanker
President
Z & B Enterprises, Inc.
12154 Darnestown Road, #236
GAITHERSBURG MD 20878

Re: K233977
Trade/Device Name: Velacur
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: August 1, 2024
Received: August 2, 2024

Dear Rhona Shanker:

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.

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,

Marjan Nabili -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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)*
K233977

Device Name
Velacur

Indications for Use *(Describe)*
Velacur is intended to provide estimates of tissue stiffness generated from shear wave speed measurements (40-70 Hz), ultrasound attenuation and Velacur Determined Fat Fraction (VDFF). The Velacur Determined Fat Fraction combines ultrasound attenuation and backscatter coefficient measurements. The device is indicated to non-invasively determine liver tissue stiffness, attenuation, and Velacur Determined Fat Fraction. VDFF is not intended to be used in pediatric patients. These are meant to be used in conjunction with other clinical indicators in order to aid in clinical management of patients with liver diseases, including hepatic steatosis.

The device is intended to be used in a clinical setting and by trained medical professionals.

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.

Section 5 – 510(k) Summary **K233977**

Sonic Incytes Velacur system

I. Submitter:

Sonic Incytes
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Vancouver, BC V6J 1P2 Canada
Telephone: +1 604 875 4111 Extension: 54851

Contact person: Rhona Shanker
Date Prepared: 15 December 2023

II. Device

Name of Device: Velacur

Model: LI-1005

Common Name: Ultrasound elastography system

Classification Name	Regulation	Product Code
Ultrasonic Pulsed Echo Imaging System	21 CFR §892.1560	IYO
Diagnostic Ultrasonic Transducer	21 CFR §892.1570	ITX

Predicate Device

Velacur (K232459) manufactured by Sonic Incytes Medical Corp., Vancouver, Canada, and cleared on September 12, 2023.

Reference device: Siemens Acuson Sequoia (K183575) cleared on March 20, 2019.

Device Description

The device that is the subject of this submission is the same one cleared under K232459, Velacur.

Velacur is a portable device intended to non-invasively measure the stiffness and attenuation of the liver via measurement of liver tissue shear modulus and ultrasound attenuation. This is done by measuring the wavelength or wave speed of mechanically created shear waves within the organ of the patient. Attenuation is measured directly via the loss in power of the ultrasound beam.

The device is designed to be used at the point of care, in clinics and hospitals. The device is used by a medical profession, an employee of the clinic/hospital. The activation unit is placed under the patient, while lying supine on an exam bed. The activation unit vibrates at frequencies 40, 50, and 60 Hz causing shear waves within the liver of the patient. The ultrasound transducer is placed on the patient's skin, over the intercostal space, and is used to take

volumetric scans of the liver while shear waves are occurring. The device includes two algorithms designed to help users detect good quality shear waves and identify liver tissue. From the scan data, the device calculates tissue stiffness and attenuation.

Minor hardware and software changes were made to the device. The organ guide (cleared in K223287) was also extended to add more optional overlays on top of the liver overlay to help with optimizing the scan and training users to obtain adequate images. The significant change is the addition of a new output measure for Velacur, an ultrasound derived fat fraction (VDFF).

Intended Use/ Indication for Use

Velacur is intended to provide estimates of tissue stiffness generated from shear wave speed measurements (40-70 Hz), ultrasound attenuation and Velacur Determined Fat Fraction (VDFF). The Velacur Determined Fat Fraction combines ultrasound attenuation and backscatter coefficient measurements. The device is indicated to non-invasively determine liver tissue stiffness, attenuation, and Velacur Determined Fat Fraction. VDFF is not intended to be used in pediatric patients. These are meant to be used in conjunction with other clinical indicators in order to aid in clinical management of patients with liver diseases, including hepatic steatosis.

The device is intended to be used in a clinical setting and by trained medical professionals.

Substantial Equivalence

The candidate device has the same intended use and indications for use as the predicate device in that the outputs are meant to be used in conjunction with other clinical indicators in order to aid in clinical management of patients with liver diseases.

The technology used in the candidate and predicate device is based on ultrasound to measure elastography and attenuation (ACE). The systems measure the same physical variables, tissue stiffness and ultrasound attenuation, and therefore the devices are substantially equivalent in their basic technology.

Sonic Incytes has introduced a third Velacur output, the Velacur Determined Fat Fraction (VDFF), in addition to the elasticity and ACE output. The Siemens Sequoia Ultrasonically Derived Fat Fraction (UDFF) was used as the reference device for this output measure. The same as UDFF, the VDFF algorithm combines ultrasound attenuation measurements and a computed backscatter coefficient (BSC). The same as UDFF, MRI proton density fat fraction was used as the ground truth for validation. The performance testing acceptance criteria were based on UDFF testing and results.

The candidate device with the described changes does not raise any new issues of safety or effectiveness.

Performance Data

The following testing was performed:

- Performance verification testing of the Velacur Determined Fat Fraction output
- Backscatter testing on phantoms, using phantoms with known backscatter parameters
- Sweep guidance tool testing

- Human Factors testing
- Validation testing of the organ guide extension
- Software Verification and Validation

Recognized Consensus Standards Used

The system complies with the same standards as the predicate, the standards are:

IEC 60601-1-2 Edition 4.1: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

ANSI AAMI 60601-1:2005/(R)2012 And A1:2012: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)

IEC 60601-1-6 Edition 3.1 2013-10: Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability

IEC 62304:2006/A1:2015: Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)

IEC 60601-2-37 Edition 2.1 2015 Medical Electrical Equipment - Part 2-37: Particular Requirements for The Basic Safety and Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment

IEC 62359: Edition 2.1 2017-09: Ultrasonics - Field Characterization - Test Methods for The Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields

ISO 14971 Third Edition 2019-12: Medical Devices - Application of Risk Management to Medical Devices

ISO 10993-1 fifth edition 2018-08: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within A Risk Management Process

Validation of Velacur Determined Fat Fraction algorithm (VDFF)

Velacur Determined Fat Fraction was tested in a cohort of patients with both Velacur and MRI-PDFF scans. 112 patients from 4 sites were used in for parameter fitting (training) and 70 new patients from 3 separate sites (with different Velacur operators) were used for the final validation. All MRI scans were assessed to create the final measurement.

Acceptance criteria were based on the correlation coefficient (r) between VDFF and MRI-PDFF, and the detection of 5% steatosis. Demographic distribution of the patients is summarized below:

	Parameter Fitting Cohort (Training)	Validation Cohort
Number of patients	112	70
Number of Sites	4	3

Sex (% Female)	53% Female	75.7% Female
Age (mean ± std)	57.4 ± 11.7	46.9 ± 13.8
BMI (mean ± std)	30 ± 4.4	30.9 ± 7.58
Race/Ethnicity (% white)	36 %	69 %
MRI PDFF (mean ± std)	14.2 ± 8.23	10.1 ± 9.75

The final correlation coefficient [95% CI] in the validation cohort was 0.85 [0.77-0.91]. The AUC [95% CI] for detection of 5% steatosis, which is the consensus level for the diagnosis of any steatosis, was 0.97 [0.89-0.99].

Machine Learning Validation for Organ Guide Extension

- The Organ Guide was extended to include surrounding organs and features.
- Dice Coefficient and pixel accuracy were used for characterization and validation of the performance of the organ guide extension. The acceptance criteria were:
  - Dice Coefficient > 0.7
  - Pixel accuracy > 80%
- More than 5,000 patient images were used for training. Training data was collected during clinical trials of volunteers and patients with chronic liver disease of all severities. Data was collected from sites across the US and Canada.
- Evaluation was completed on more than 800 images from 21 patients.
- Volunteers and patients were recruited from all genders, ages between 18-70 and all ethnicities, with from 33-50% minority representation.
- Evaluation data was collected from volunteers and patients with non-alcoholic fatty liver disease and non-alcoholic steatohepatitis. All patients were recruited from hepatology clinics and represent a group with more severe liver disease than the general public.
- All data was collected using the Velacur system.
- Ground truth was established using manual image segmentation by experts in the field of sonography and/or ultrasound elastography.
- Data used in the validation of the algorithm performance was obtained from separate patients, sites and collected by different users than the data used for training in order to ensure data independence.

Machine Learning Validation for Wave Quality Guide

- The Wave Quality Guide is an algorithm to measure the area of good quality waves within the image or volume. This is shown to the user through an optional semi transparent overlay, and the quality bar in the interface.
- Dice Coefficient and sensitivity/specificity were used for characterization and validation of the performance of the wave quality guide. The acceptance criteria were:
  - Dice Coefficient > 0.7
  - Sensitivity and Specificity > 80%

- More than 15,000 patient images from 100+ patients were used for training. Training data was collected during clinical trials of volunteers and patients with chronic liver disease of all severities. Data was collected from sites across the US and Canada.
- Evaluation was completed on more than 4,000 images from 36 patients.
- Volunteers and patients were recruited from all genders, ages between 18-70 and all ethnicities, with from 33-50% minority representation.
- Evaluation data was collected from volunteers and patients with non-alcoholic fatty liver disease and non-alcoholic steatohepatitis. All patients were recruited from hepatology clinics and represent a group with more severe liver disease than the general public.
- All data was collected using the Velacur system.
- Ground truth was established using manual image segmentation by experts in the field of ultrasound elastography.
- Data used in the validation of the algorithm performance was obtained from separate patients, sites and collected by different users than the data used for training in order to ensure data independence.

Conclusion

The conclusion drawn from the testing described above demonstrate that the device is substantially equivalent to the predicate device with respect to safety, effectiveness and performance.