June 26, 2025

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

Re: K251728
Trade/Device Name: Velacur One (LI-1100)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 4, 2025
Received: June 5, 2025

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
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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)*
K251728

Device Name
Velacur One (LI-1100)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 – 510(k) Summary
K251728
Sonic Incytes Velacur ONE system

I. Submitter:

Sonic Incytes
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Telephone: +1 604 875 4111 Extension: 54851

Contact person: Rhona Shanker
Date Prepared: 04 June 2025

II. Device

Name of Device: Velacur ONE

Model: LI-1100

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 (K233977) manufactured by Sonic Incytes Medical Corp., Vancouver, Canada, and cleared on September 4, 2024.

Device Description

The device that is the subject of this submission is the substantially equivalent to that cleared under K233977, Velacur.

Velacur ONE 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 and Velacur Determined Fat Fraction is a combination of measured ultrasound attenuation and backscatter.

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.

Software and hardware changes were made to the device. The intended use of the device is unchanged. The user interface was updated to a more modern platform with the same workflow and outputs. The hardware components have been consolidated, combining the functionality of the computing unit and control unit. The activation unit has been designed to include more voice coils which are distributed throughout the unit. The power output and performance of the activation unit is unchanged.

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, attenuation (ACE) and Velacur Determined Fat Fraction (VDFF). The systems measure the same physical variables, tissue stiffness and ultrasound attenuation, and therefore the devices are substantially equivalent in their basic technology.

The hardware and software changes have been validated in the same manner as the predicate.

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

The Table below compares relevant characteristics of the above devices.

	Proposed Device	**Predicate Device** K233977	**Comment**
Description	Velacur ONE – 1100	Velacur- 1005	
Company	Sonic Incytes	Sonic Incytes	Same

	Proposed Device	Predicate Device K233977	Comment
Indications of 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.	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.	Same
Imaging Method	Pulse-echo based ultrasound	Pulse-echo based ultrasound	Same
Technological Characteristics (General)	The system uses an external shear wave generator to produce shear waves at 40-70Hz within the abdominal cavity. Ultrasound imaging is used to acquire the wave field over a volume and to measure the tissue stiffness over a volume. Analysis of the ultrasound radio-frequency (RF) data is used to estimate tissue attenuation and backscatter coefficient, which are combined to measure Velacur Determined Fat Fraction (VDFF).	The system uses an external shear wave generator to produce shear waves at 40-70Hz within the abdominal cavity. Ultrasound imaging is used to acquire the wave field over a volume and to measure the tissue stiffness over a volume. Analysis of the ultrasound radio-frequency (RF) data is used to estimate tissue attenuation and backscatter coefficient, which are combined to measure Velacur Determined Fat Fraction (VDFF).	Same

	Proposed Device	Predicate Device K233977	Comment
Shear Wave Generation	External vibration source on the skin	External vibration source on the skin	Same
Shear Wave Frequencies	40 -70Hz	40 -70Hz	Same
Shear Wave type	Steady state mechanical waves	Steady state mechanical waves	Same
Vibration signal characteristics	Steady state superimposed multi-frequency signal	Steady state superimposed multi-frequency signal	Same
Elasticity averaging	3D Elasticity output computed as an average of all the shear moduli computed at each pixel in the ROI	3D Elasticity output computed as an average of all the shear moduli computed at each pixel in the ROI	Same
Attenuation Measurement Algorithm	Spectral Shift Reference Phantom method	Spectral Shift Reference Phantom method	Same
Liver Fat fraction Estimate	Estimates liver fat using a combination of attenuation and backscatter	Estimates liver fat using a combination of attenuation and backscatter	Same
Liver Fat Fraction Validation	Fat fraction estimate is validated against MRI PDFF as the reference standard	Fat fraction estimate is validated against MRI PDFF as the reference standard	Same
Output/Visualization	Image with measurement of 3D tissue stiffness, ultrasound attenuation and Velacur determined fat fraction (VDFF)	Image with measurement of 3D tissue stiffness, ultrasound attenuation and Velacur determined fat fraction (VDFF)	Same
Patient Population	Ages 2 and above for stiffness and attenuation, 18 and up for VDFF	Ages 2 and above for stiffness and attenuation, 18 and up for VDFF	Same
User certification	Medical professional trained for using Velacur ONE	Medical professional trained for using Velacur	Same
Required User interactions	User holds the probe against the skin, and software (shown on the laptop display) including the optional overlay from machine learning algorithms is shown on the device display to indicate when the location is acceptable.	User holds the probe against the skin, and software (shown on the laptop display) including the optional overlay from machine learning algorithms is shown on the device display to indicate when the location is acceptable.	Same

	Proposed Device	Predicate Device K233977	Comment
	User moves the probe in sweep motion.	User moves the probe in sweep motion.	
Patient interaction	Patient lays supine, holds breath during image acquisition. Scan is performed intercostally.	Patient lays supine, holds breath during image acquisition. Scan is performed intercostally.	Same
Use Environment	Clinic and Hospital	Clinic and Hospital	Same
Time for acquisition	5-10 minutes	5-10 minutes	Same
Types of images displayed	Ultrasound B-Mode image	Ultrasound B-Mode image	Same
Other displayed information to the user, e.g., information displayed to indicate the measurement will be valid	Yes, overall quality of image and tracking. Warning message if quality is too low. Ultrasound B-Mode image with overlays to indicate where the liver and acceptable shear waves are located	Yes, overall quality of image and tracking. Warning message if quality is too low. Ultrasound B-Mode image with overlays to indicate where the liver and acceptable shear waves are located	Same
Information displayed to indicate that the location is acceptable for imaging	Yes	Yes	Same
Cybersecurity	Evaluated using OWASP IoT best practices, NIST SP 800-53, ISO/IEC 27002, ISO/IEC 80001-1, FDA guidelines; OSSTMM-based network testing; testing per IEC 81001-5-1:2021 and EMA 726/2004. Testing included functional, boundary, and stress testing. Determined to have adequate security controls.	Evaluated using the same methodologies: OWASP IoT best practices, NIST SP 800-53, ISO/IEC 27002, ISO/IEC 80001-1, FDA and PHAC guidelines; network infrastructure testing per OSSTMM; IEC 81001-5-1:2021 and EMA 726/2004 compliant. Testing included penetration, vulnerability, stress, boundary, and functional assessments. Concluded to have added security controls	Equivalent: same security testing standards and methodol-ogy used. Proposed device demonstra-ted robust cyberse-curity protection.

	Proposed Device	Predicate Device K233977	Comment
Number of Components	3	4	Mobile computing unit has been integrated into the control unit to create a single Core unit
Power requirements	110V (wall power)	110V (wall power)	Same
Battery	Internal (non-removable) battery to provide back-up power and allow device to function as designed for approximately 20 minutes.	Relied on laptop battery for back-up power for computing unit	Internal battery is part of the new Core Unit design with improved functionality. Battery is IEC 62133-2:2017 certified
EMC compliance	IEC 60601-1-2:2020 Edition 4.1	IEC 60601-1-2:2020 Edition 4.1	Same

Performance Data

The following testing was performed:

- Bench testing of the stiffness, attenuation and VDFF measures on reference phantoms using the same test methods and acceptance criteria as the predicate
- Human Factors testing on software and hardware
- Shipping and packaging testing
- Performance and human factors testing of the new activation unit design
- Software Verification and Validation

No clinical or animal testing was performed.

Bench Testing Validation for Elasticity, Attenuation and VDFF Algorithms

Bench testing validation for the algorithms is summarized below:

Elasticity

The elasticity was validated using 6 Homogeneous phantoms with different stiffness values.

The overall bias to the CIRS values was used as a comparison point for both systems to determine the substantial equivalence of Velacur ONE to the predicate. The average difference between the bias of Velacur ONE and the predicate was 2.45%.

The precision of the predicate ranged from 1.1% to 2.6% with an average of 2.1%. In comparison, Velacur ONE had an average precision of 1.7% with a min and max of 0.3% and 2.9% respectively.

The device demonstrated equivalent accuracy and precision to the predicate and met all criteria necessary to support clinical suitability.

The results of the Bland-Altman plots show excellent correlation between the measurements and that no value falls outside the 1.96*STD lines.

The results of the two systems both passed the defined acceptance criteria when being compared to each other and are considered substantially equivalent.

Attenuation

The attenuation algorithm was validated using 6 attenuation phantoms that span the expected range of attenuation values in human liver.

The overall bias was the basis on which the two algorithms are compared to the expected values. The overall bias for the Velacur ONE algorithm was 9.1% compared to the Velacur overall bias of 8.0%. Both have an overall bias less than the 10% acceptance criteria.

The mean precision value across all the phantoms was 0.9% for Velacur and 0.6% for Velacur ONE. The maximum precision for Velacur ONE was less than 10%.

Velacur Determined Fat Fraction algorithm (VDFF)

Velacur Determined Fat Fraction (VDFF) was compared to the calculated expected VDFF based on the labeled backscatter and attenuation for 6 different phantoms, with a variety of backscatter coefficients at 3MHz from 7.01e-3 cm-1sr-1 to 4.24e-4 cm-1sr-1.

The overall bias for Velacur ONE was 8%, compared to the predicate bias of 9% in the phantoms, or were clinically meaningful cutoff value for any steatosis of 5%. The overall (maximum) precision (5.4 %) was less than 10%. The Velacur ONE passes this performance test in all measured phantoms.

The Pearson correlation coefficient, r, of the Velacur VDFF measurement when compared to the expected VDFF value was 0.95. The Pearson correlation coefficient is greater than 0.8 and so the Velacur VDFF measurement passes this performance test.

Human Factors testing on software and hardware

Human Factors testing completed on the new software and hardware form factor included two rounds of formative testing (using a hardware mock up and then just the interface) and a final summative test.

No new critical tasks or hazardous use scenarios were encountered. Minor software difficulties were encountered, but all were easily corrected. Descriptions of these software features have been added to the training of operators to ensure no errors or difficulties will be encountered.

IEC 60601-1-6 Edition 3.1 was used as the basis for this evaluation. The risk-based assessment of modifications made and preliminary formative testing rounds and summative testing of Velacur ONE support the conclusion that Velacur ONE is safe and effective for the intended users, uses, and use environments.

Recognized Consensus Standards Used

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

IEC 60601-1-2 Edition 4.1 2020-09: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

IEC 60601-1 Edition 3.2 2020-08: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-6 Edition 3.2 2020-07: Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability

IEC 62304 Edition 1.1 2015-06: Medical Device Software - Software Life Cycle Processes

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

IEC 62133-2 Edition 1.0 2017-02: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 2: Lithium systems

Conclusion

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