September 12, 2023

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

Re: K232459
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 14, 2023
Received: August 15, 2023

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232459

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) and coefficient of attenuation. The device is indicated to non-invasively determine liver tissue stiffness and attenuation. These are meant to be used in conjunction with other clinical indicators in order to assist in clinical management of patients with liver disease. The device is intended to be used in a clinical setting and by appropriately 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.

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Section 5 – 510(k) Summary

Sonic Incytes Velacur system **K232459**

I. Submitter:

Sonic Incytes
#309-1788 West 5th Avenue
Vancouver, BC V6J 1P2 Canada
Telephone: +1 604 875 4111 Extension: 54851

Contact person: Rhona Shanker
Date Prepared: 11 August 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 (K223287) manufactured by Sonic Incytes Medical Corp., Vancouver, Canada, and cleared on April 20, 2023.

Device Description

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.

The significant change was optimization of the elasticity and attenuation calculations by implementing alternate scientifically established methods while maintaining the same output measurements.

Intended Use/ Indication for Use

Velacur is intended to provide estimates of tissue stiffness generated from shear wave speed measurements (40-70Hz) and coefficient of attenuation. The device is indicated to non-invasively determine liver tissue stiffness and attenuation. These are meant to be used in conjunction with other clinical indicators in order to assist in clinical management of patients with liver disease. The device is intended to be used in a clinical setting and by appropriately trained medical professionals.

Substantial Equivalence

The candidate device has an equivalent intended use and indications for use as the predicate device.

The technology used in the candidate and predicate device is based on ultrasound to measure elastography and attenuation. 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 optimized the core algorithms that measure tissue stiffness and ultrasound attenuation. These changes were made by implementing alternate scientifically established methods while maintaining the same output measurement.

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

Performance Data

The following non-clinical testing was performed:

- The validation of the changes from the predicate were tested and documented based on the tests performed on phantoms with known elasticity and attenuation.

Specifically, non-clinical bench testing included:

- Performance verification testing
- Elasticity testing on phantoms, with comparison to magnetic resonance elasticity and/or predicate device
- Attenuation testing with phantoms, using phantoms with known attenuation

No animal or clinical performance was performed.

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

Bench Testing Validation for Elasticity and Attenuation Algorithms

Bench testing validation for both algorithms is summarized below:

Elasticity

Homogeneous Elasticity Phantoms

The methods used to measure the stiffness with both MRE and Velacur show comparable results which are within the acceptance criteria for stiffness for 4 phantoms of various elasticities. The maximum bias between MRE and Velacur was less than 10% and the precision was less than 2%.

In addition, when comparing the accuracy of the proposed algorithm with the predicate, the Bland-Altman plots show that no value falls outside the 1.96*STD lines.

Homogeneous Elasticity Phantom without a solid container

Elasticity bench testing was done on a “boundary-less” phantom to ensure that the proposed algorithm is not affected by boundary conditions specific to the phantoms. The bias between the measurements on the phantom without a solid container with the proposed device was less than the 10% acceptance criterion. The precision of the device with the proposed algorithm using the same phantom was 0.8%, which is within the acceptance criteria of 10%.

Attenuation

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

The overall bias (in comparison to the phantom specification for attenuation) for the proposed algorithm was 3.86%, which was less than the predicate. The maximum bias was 5.21% for the proposed Velacur attenuation algorithm which is less than the 10% acceptance criterion.

The maximum precision seen with the proposed Velacur attenuation algorithm was 3.22%. The mean precision value across all the phantoms was 2.02% for the proposed Velacur attenuation algorithm, both below the acceptance criterion of 10%.

Conclusion

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