April 20, 2023

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

Re: K223287
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: March 17, 2023
Received: March 17, 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
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)*
K223287

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.

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

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: 19 April 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

Liver Incytes (K201597) manufactured by Sonic Incytes Medical Corp., Vancouver, Canada, and cleared on July 31, 2020.

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 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. From the scan data, the device calculates tissue stiffness and attenuation.

Minor hardware and software changes were made to the device. One such change was the change in the vibration frequencies produced by the activation unit to create shear waves in the liver. The shear waves are now produced at 40, 50, and 60 Hz, as compared to the predicate device (45, 50, 55, 60Hz). The significant change was the addition two deep learning based algorithms. The first being an organ/liver segmentation algorithm. The second algorithm changes the predicate's rules-based scan quality to a deep learning based shear wave quality algorithm. These algorithms are designed to help users better detect good quality shear waves and identify liver tissue, to facilitate the data collection for elasticity and attenuation calculations performed by the device. The organ/liver segmentation algorithm can only segment the liver if the liver is present in the B-Mode ultrasound image and should not be used as a liver detection algorithm. The shear wave quality algorithm was tested to both detect and segment the shear waves. These elasticity and attenuation calculations were cleared in the predicate device.

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.

Substantial Equivalence

The candidate device has an equivalent intended use and indications for use as the predicate device. Further, it has the same operating principle.

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. 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:

- Electrical safety, electromagnetic interference
- The validation of the changes from the predicate were tested and documented based on the tests performed on phantoms with known elasticity and attenuation. Design changes were also tested against the predicate design on healthy volunteers.
- The candidate device was tested in a cohort of patients and volunteers with several novice users.

Specifically, non-clinical bench testing included:

- Performance verification testing
- Attenuation testing with phantoms

- Inter-operator variability
- Human Factors testing
- Device Lifespan analysis
- Sweep guidance tool testing
- Software feature testing: Quality Factor, Organ Segmentation Guide and Wave Quality Guide.

Recognized Consensus Standards Used

Non-clinical testing to assure compliance with EMC was performed and the device was found to conform to the applicable medical device safety standard. The system complies with

- Electromagnetic compatibility (EMC) testing.
    - o IEC 60601-1-2 Edition 4.0 (only the potentially affected tests by the changes)

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

Artificial Intelligence/Machine Learning Validation for Organ Segmentation Guide and Wave Quality Guide

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance

- Dice Coefficient, pixel accuracy, and sensitivity and specificity were used for validation and characterization of the performance of the algorithms. Both algorithms were validated on patient data from the US and Canada.
    - For the Organ Segmentation Guide, the average Dice Score was greater than 0.7, and overall pixel based accuracy was greater than 80%.
    - For the Wave Quality Guide, the Dice Scores and sensitivity/specificity were used to measure algorithm performance in segmentation and detection. The Dice Scores were 0.7 or higher and the sensitivity and specificity was 80% or greater.
- More than 5,000 patient images were used for training each algorithm. 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 1,500 images, from 35-40 patients.

Demographic distribution including:

- Volunteers and patients were recruited from all genders, ages between 18-70.
- Volunteers and patients of all ethnicities were included, with 33-50% minority representation.
- Data was collected from sites in the US and Canada

Information about clinical subgroups and confounders present in the dataset:

- 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.

Information about equipment and protocols used to collect images:

- All data was collected using the Velacur system, with comparison to Magnetic Resonance Elastography or Magnetic Resonance Proton Density Fat Fraction where appropriate.

Information about how the reference standard was derived from the dataset (i.e., the “truthing” process)

- Ground truth was established using manual image segmentation by experts in the field of sonography and/or ultrasound elastography.
- For the Organ Segmentation Guide, all validation images were segmented by at least three sonographers who all had more than 20 years experience in abdominal ultrasound imaging. Ground truth was established using a pixel based voting method.
- For the Wave Quality Guide, all experts hold a masters or PhD in a relevant field. All experts have at least 10 years of experience with ultrasound imaging and elastography. Ground truth was established through expert consensus.

Description of how independence of test data from training data was ensured

- Data used in the evaluation of the algorithm performance was taken from separate patients, sites and collected by different users than the data used for training in order ensure data independence.