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

July 31, 2020

Re: K201597
Trade/Device Name: Liver Incytes, Model 1005
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 10, 2020
Received: June 12, 2020

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201597

Device Name
Liver Incytes, Model 1005

Indications for Use *(Describe)*

The Liver Incytes System 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.

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

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Diagnostic Ultrasound Intended Use

System: Liver Incytes, Model 1005

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General	**Specific**	**B**	**M**	**PWD**	**CWD**	**Colour Doppler**	**Combined (Specify)**	**Other[1] (Specify)**
Ophthalmic	Ophthalmic	-	-	-	-	-	-	-
Fetal Imaging & Other	Fetal	-	-	-	-	-	-	-
	Abdominal	N	-	-	-	-	-	N
	Intra-operative (Specify)	-	-	-	-	-	-	-
	Intra-operative(Neuro)	-	-	-	-	-	-	-
	Laparoscopic	-	-	-	-	-	-	-
	Pediatric	-	-	-	-	-	-	-
	Small Organ (Specify)	-	-	-	-	-	-	-
	Neonatal Cephalic	-	-	-	-	-	-	-
	Adult Cephalic	-	-	-	-	-	-	-
	Trans-rectal	-	-	-	-	-	-	-
	Trans-vaginal	-	-	-	-	-	-	-
	Trans-urethral	-	-	-	-	-	-	-
	Trans-esoph. (Non-Card.)	-	-	-	-	-	-	-
	Musculo-skel (conventional)	-	-	-	-	-	-	-
	Musculo-skel (superficial)	-	-	-	-	-	-	-
	Intra-luminal	-	-	-	-	-	-	-
	Other (Specify)	-	-	-	-	-	-	-
Cardiac	Cardiac Adult	-	-	-	-	-	-	-
	Cardiac Pediatric	-	-	-	-	-	-	-
	Trans-Esoph. (Cardiac)	-	-	-	-	-	-	-
	Other (Specify)	-	-	-	-	-	-	-
Peripheral	Peripheral vessel	-	-	-	-	-	-	-
Vessel	Other (Specify)	-	-	-	-	-	-	-

N = New indication for this submission

1 = Elastography mode

510(k) Summary

Sonic Incytes Liver Incytes system

K201597

I. Submitter:

Sonic Incytes
560-828 West 10th Avenue
Vancouver, BC V5Z 1M9 Canada
Telephone: +1 604 875 4111 Extension: 54851

Contact person: Rhona Shanker
Date Prepared: 5 June 2020

II. Device

Name of Device: Liver Incytes, Model 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

Predicate Device: EchoSens FibroScan® (K160524) manufactured by EchoSens, Paris, France, and cleared on March 18, 2016.

Reference device: Magnetic Resonance Elastography (K140666) is used as the reference device for some performance testing.

Device Description

Liver Incytes is a non-invasive ultrasound based device for measuring tissues stiffness and ultrasound attenuation in patients with chronic liver disease. The device uses ultrasound measurements of shear wave speed in the tissues to estimate stiffness. The attenuation is measured through the ultrasound signal itself.

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.

Intended Use/ Indication for Use

The Liver Incytes System 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.

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, predicate device and reference 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 accuracy and precision of the device were found to be substantially equivalent to those of the predicate device and reference device (MRI Elastography). The new device does not raise any new issues of safety or effectiveness.

Performance Data

The following non-clinical testing was performed and submitted:

- Electrical safety, electromagnetic interference and ultrasound
- The accuracy and precision of the device was tested and documented based on tests performed on phantoms with known elasticity and attenuation.
- The proposed device was tested in a small cohort of healthy volunteers with several novice users. This usability study showed that the device could be used successfully on volunteers with Body Mass Index from 25 to 43 kg/m2, representing the intended patient population. The users who participated in this study were representative of the intended use population.

Recognized Consensus Standards Used

Non-clinical testing to assure compliance with acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety were performed and the device was found to conform to applicable medical device safety standards. The system complies with the following standards:

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 60601-1-2 Edition 4.0	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
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]

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 Second Edition 2007-03-01	Medical Devices - Application Of Risk Management To Medical Devices (CL 4.2 from 60601-1)
ISTA 3A 2008	Packaged-Products For Parcel Delivery System Shipment 70 Kg (150 Lb) Or Less
ISO 10993-1 Fourth Edition 2009-10-15	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

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.