Ontact Health Co., Ltd.
Hyuk-Jae Chang
CEO
5f, 50-5, Ewhayeodae-gil, Seodaemun-gu
Seoul, KS013/03764
Korea, South

October 20, 2023

Re: K230209
Trade/Device Name: Sonix Health
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: October 19, 2023
Received: September 21, 2023

Dear Hyuk-Jae Chang:

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.

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,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
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)*
K230209

Device Name
Sonix Health

Indications for Use *(Describe)*
Sonix Health is intended for quantifying and reporting echocardiography for use by or on the order of a licensed physician. Sonix Health accepts DICOM-compliant medical images acquired from ultrasound imaging devices. Sonix Health is indicated for use in adult populations.

Ultrasound images are acquired via the B (2D), M, Pulsed-wave Doppler, and Continuous-wave Doppler modes.

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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510(k) Summary

[As required by 21 CFR 807.92]

1. Date

October 19, 2023

2. Submitter's Information & Contact Person

- Submitter: ONTACT HEALTH Co., Ltd.
- Address: 5F Erom Tower, 50-5, Ewhayeodae-gil, Seodaemun-gu, Seoul, 03764, Republic of Korea
- Contact Person: Hyuk-Jae Chang / CEO
- Telephone No.: +82-2- 362-9610
- Email Address: ontact01@ontacthealth.com

3. Trade Name, Common Name, Classification

- Common name: Workstation Software for cardiac ultrasound image review, analysis, and reporting
- Trade name: Sonix Health

Classification Description	21 CFR Section	Product Code
Automated Radiological Image Processing Software	21 CFR 892.2050	QIH, LLZ

As stated in 21 CFR parts 892.2050 of the device has been classified as Class II.

4. Identification of Predicate Device(s)

The identified predicate devices within this submission are shown as follow:

Predicate Device

- 510(k) Number: K213544
- Trade/Device name: TOMTC-ARENA
- Manufacturer: TOMTEC Imaging Systems GmbH

Reference Device

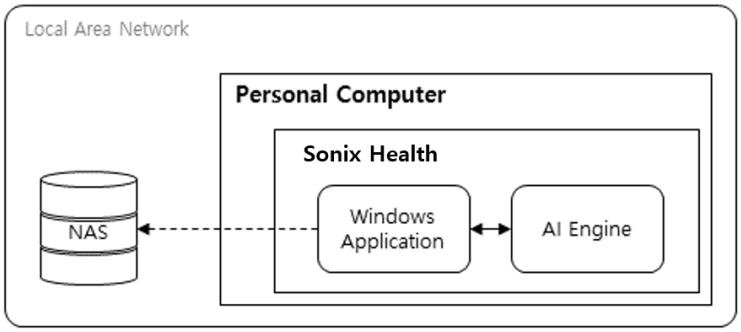
- 510(k) Number: K220975
- Trade/Device name: V8 Diagnostic Ultrasound System,
- Manufacturer: Samsung Medison Co., Ltd.

5. Description of the Device

Sonix Health comes with the following functions:

- Checking ultrasound multiframe DICOM
- Echocardiography multiframe DICOM classification and automatic measurement.
- Verification of the results and making adjustments manually.
- Providing the report for analysis

Sonix Health will be offered as SW only, to be installed directly on customer PC hardware. Sonix Health is DICOM compliant and is used within a local network.



Sonix Health utilizes a two-step algorithm. A single identification model identifies a view in the first step. The second step performs the deep learning algorithm according to the view. The deep learning algorithms for the second step are categorized as B-mode, M-mode, and Doppler algorithms. The main algorithm of Sonix Health is to identify the view and segment the anatomy in the image.

6. Indications for Use

Sonix Health is intended for quantifying and reporting echocardiography for use by or on the order of a licensed physician. Sonix Health accepts DICOM-compliant medical images acquired from ultrasound imaging devices. Sonix Health is indicated for use in adult populations.

Ultrasound images are acquired via the B (2D), M, Pulsed-wave Doppler, and Continuous-wave Doppler modes.

7. Determination of Substantial Equivalence

The identified predicate devices within this submission is shown in the following table:

Description	Decision	Subject Device (K230209)	Predicate Device (K213544)	Reference Device (K220975)
Trade/Device name		Sonix Health	TOMTEC-ARENA	V8 Diagnostic Ultrasound System
Product Code		QIH (Subsequent Product Code: LLZ)	QIH (Subsequent Product Code: LLZ)	IYN, IYO, ITX
Regulatory Class	SE	2	2	2
Regulation Number	-	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.1550, 892.1560, 892.1570
Intended use	SE	Sonix Health is intended for quantifying and reporting echocardiography for use by or on the order of a licensed physician. Sonix Health accepts DICOM-compliant medical images acquired from ultrasound imaging devices. Sonix Health is indicated for use in adult populations. Ultrasound images are acquired via the B (2D), M, Pulsed-wave Doppler, and Continuous-wave Doppler modes.	TOMTEC-ARENA software is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities. TOMTEC ARENA is not intended to be used for reading of mammography images.	The V8 / V7 diagnostic ultrasound system and probes are designed to obtain ultrasound images and analyze body fluids. The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Thoracic, Trans-esophageal (Cardiac) and Peripheral vessel. It is intended for use by, or by the order of, and under the supervision of, an appropriately trained healthcare professional who is qualified for direct use of medical devices. It can be used in hospitals, private practices, clinics and similar care environment for clinical diagnosis of patients. Modes of Operation: 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, Combined modes, Multi-Image mode (Dual, Quad), 3D/4D mode.
Indications for use	SE		Indications for use of TOMTEC-ARENA TTA2 software are quantification and reporting of cardiovascular, fetal, abdominal structures and function of patients with suspected disease to support the physician in the diagnosis	
Where used (hospital, home, ambulance, etc.)	SE	Inside of hospitals, clinics, and physician's offices.	Inside and outside of Hospitals, Clinics, and Physician's offices.	Inside of hospitals, clinics, and physician's offices.
Application description	SE	Sonix Health utilizes artificial intelligence to automate previous manual quantification tasks, resulting in increased efficiency for users. Our system performs view	IMAGE-COM is a basic module for reviewing and measuring digital medical data. It supports routine workflows for loading, analyzing and	The V8 / V7 are a general purpose, mobile, software controlled, diagnostic ultrasound system. Their function is to acquire ultrasound data and to display the data as 2D mode,Color Doppler mode,

Description	Decision	Subject Device (K230209)	Predicate Device (K213544)	Reference Device (K220975)
		classification and measurements according to the US ASE guidelines, and the users can review and modify the results if necessary.	saving medical studies, e.g. for the purpose of creating reports. IMAGE-COM is where basic measurements can be performed and the entry point for advanced analysis modules. Study related routine measurements can be imported, displayed, edited and exported to accompanying reporting systems.	Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode. The V8 / V7 also give the operator the ability to measure anatomical structures and offer analysis packages that provide information that is used to make a K223387 Traditional 510(k) diagnosis by competent health care professionals. The V8 / V7 have a real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.
Semi-automated view classification	SE	PLAX LV, A4C, A4C Zoomed LV, A2C, A2C zoomed LV, M-mode LA/Ao, M-mode LV, CW Doppler MS, CW Doppler MR, PW Doppler MV, CW Doppler AV, CW Doppler AR, CW Doppler TR, CW Doppler PV, CW Doppler PR, PW Doppler RVOT, PW Doppler LVOT, DTI MV annulus	-	PLAX LV, A4C, A4C Zoomed LV, A2C, A2C zoomed LV, M-mode LA/Ao, M-mode LV, CW Doppler MS, CW Doppler MR, PW Doppler MV, CW Doppler AV, CW Doppler AR, CW Doppler TR, CW Doppler PV, CW Doppler PR, PW Doppler RVOT, PW Doppler LVOT, DTI MV annulus
Semi-automated measurements	SE	IVSd (2D), IVSs (2D), LVIDd (2D), LVIDs (2D), LVPWd (2D), LVPWs (2D), LA (2D), Ao (2D), LVESV / LVEDV (4CH), LAV (4CH), LVESV / LVEDV (4CH), LVESV / LVEDV (2CH), LAV (2CH), LVESV / LVEDV (2CH), LA (m-mode), Aorta (m-mode), IVSd (m-mode), LVIDd (m-mode), LVPWd (m-mode), IVSs (m-mode), LVIIDs (m-mode), LVPWs (m-mode), MV Peak E Vel, MV Peak A Vel, MV Decel Time, e' (med), a' (med), s' (med), LVOT Vmax, LVOT VTI, RVOT Vmax, RVOT VTI, PV AccT, TR Vmax, TR VTI, AR Vmax / PR Vmax, AR PHT / PR PHT, MV Vmax, MV VTI, MV, PHT, MR Vmax, MR VTI, AV Vmax / PV Vmax, AV VTI / PV VTI, RVOT (2D)	B-Mode - Ao Asc diam, Ao Ann diam, Ao STJ diam, Ao SV diam, IVSd, LA diam systole, LVIDd, LVIDs, LVOT diam, LVPWd, RVDd base (RVD1), RVDd mid (RVD2), RVLd, RVOT diam lax, RVOT diam prox, TV Ann diam ant-post, IVSd-LVIDd-LVPWd (Same line) DOPPLER Mode - MV A Vel, MV E Vel, MV E/A Slope, (MV A Vel, MV E Vel, MV Time), MV Dec. Slope, (MV Dec Time, MV E Vel), LVOT VTI, AV VTI, PV VTI, TR Vmax, LV E'(l), LV A'(l), LV E'(s), LV A'(s), RV A'(l), RV E'(l), RV S'(l)	(PLAX LV) - Interventricular septum diameter at the diastole and systole phase, LV internal diameter at the diastole and systole phase, LV posterior wall diameter at the diastole and systole phase, Aorta diameter and LA diameter, (A4C) - LA Volume, LV Volume, (A4C Zoomed LV) - LV Volume, (A2C) - LA Volume, LV Volume, (A2C zoomed LV) - LV Volume, (M-mode LA/Ao) - LA diameter and Aorta diameter, (M-mode / LV) - Interventricular septum diameter at the diastole and systole phase, LV internal diameter at the diastole and systole phase, LV posterior wall diameter at the diastole and systole phase, (CW Doppler MS) - Vmax, VTI, PHT, (CW Doppler MR) - Vmax, VTI, (PW Doppler MV) - E, A, DT, (CW Doppler AV) - Vmax, VTI, (CW Doppler AR) - Vmax, PHT, (CW Doppler TR) - Vmax, VTI, (CW Doppler PV) - Vmax, VTI, (CW Doppler PR) - Vmax, EDV, (PW Doppler RVOT) - Vmax, VTI, (PW Doppler LVOT) - Vmax, VTI, (DTI MV annulus) - S', E', A'

Description	Decision	Subject Device (K230209)	Predicate Device (K213544)	Reference Device (K220975)
Semi-automation technology	SE	After the automated analysis is complete, users can review and modify the results as needed. The product is intended for use by, or on the order of a licensed physician.	Semi-automated adult echocardiography 2D and Doppler measurements are generated using and artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements. The automation of measurements is constrained to the specific imaging mode (2D, Doppler) as recommended by ASE guidelines.	After the analysis is complete, users can review and modify the results as needed. The product is for use by, or on the order of a licensed physician.

* It is necessary for the end user to verify, confirm, and modify the analysis results when using Subject Device.

8. **Non-Clinical Test Summary**

Performance Standards

Digital Imaging and Communications in Medicine (DICOM) Set (Ps3.1 - .20)

IEC 62304:2006, Medical Device Software - Software Life Cycle Processes.

ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices.

IEC 62366-1 Edition 1.1 2020-06, Medical devices-Part 1 Application of usability engineering to medical devices.

Sonix Health is classified as a Moderate Level of Concern. The software verification and validation were conducted in compliance with IEC 62304 "Medical device software – Software life cycle process" and the internal design control process to ensure safety and effectiveness. Throughout the verification and validation process, traceability was maintained, encompassing risk management (including Cyber Security and Usability).

Sonix Health was designed to assist clinicians in adult echocardiography examinations. The training data was collected from six centers. Among these, the demographic data from the representative institution showed 50.2% male participants, an average body mass index of 22.2, and 67.0% left ventricle ejection fraction.

The training data and validation data are distinct and independent. The ground truth annotation for the test was performed by two experienced sonographers with a Registered Diagnostic Cardiac Sonographer (RDCS) certification. The annotation was supervised by two experienced cardiologists and the consensus annotation was used as the final ground truth.

For performance testing, we used 476 B-mode clinical images, 243 M-mode clinical images, and 2,025 Doppler images, resulting in a total of 2,744 test images to assess these functions. Of these, 2,648 (96.5%) were from American participants. The data was respectively collected with 1,264 (47.7 %) from a U.S. hospital and 1,384 (52.3%) from a South Korea hospital. The gender distribution for the American participants was 65% male and 35% female. Data was acquired using equipment from four major manufacturers.

The test was conducted blinded to private data, including patients' disease status. However, we measured LVEF based on the ground-truth of the validation datasets. The results showed that the left ventricle ejection fraction (LVEF) ranged from 14% to 76%, with a mean LVEF of 58% and a standard deviation of 11%. The normal LVEF (%) range for females is 54% to 74%, while for males it is 52% to 72%.

Sonix Health passed the test in two categories: an average accuracy of 98.22% for view recognition and a 93.98% average correlation coefficient when compared to manual measurements by participating experts.

Through verification and validation activities, Sonix Health is confirmed to meet all the design and performance requirements, ensuring safety and effectiveness without raising adverse issues. In conclusion, it demonstrates substantial equivalence.

Clinical Test Summary

No clinical testing conducted in support of substantial equivalence when compared to the predicate and reference devices.

9. Conclusion

In conclusion, all verification and validation activities demonstrated that the design specifications and technological characteristics of Sonix Health meet the applicable requirements and standards for the safety and effectiveness of the device for its intended use. As a result, Sonix Health is substantially equivalent to the currently marketed predicate device.