November 27, 2024

Ontact Health Co., Ltd
Seungah Lee
Division Director
5F Erom Tower, 50-5,
Ewhayeodae-gil, Seodaemun-gu
Seoul, 03764
Korea, South

Re: K240645
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: March 7, 2024
Received: November 1, 2024

Dear Seungah Lee:

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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240645

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.

K240645

510(k) Summary

[As required by 21 CFR 807.92]

1. Date

November 26, 2024

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: Seungah Lee / Division Director
- 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: K230209
- Trade/Device name: Sonix Health
- Manufacturer: ONTACT HEALTH Co., Ltd

Reference Devices

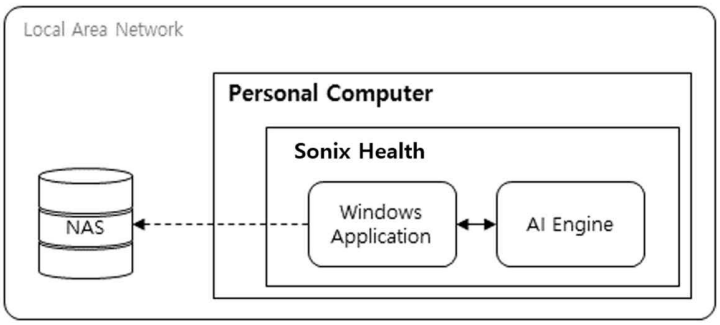
- 1. K220940: EchoPAC Software Only/ EchoPAC Plug-in
- 2. K213544: TOMTEC-ARENA

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 device within this submission is shown in the following table:

Description	Decision	Subject Device (K240645)	Predicate Device (K230209)
Trade/Device name		Sonix Health	Sonix Health
Product Code		QIH (Subsequent Product Code: LLZ)	QIH (Subsequent Product Code: LLZ)
Regulatory Class	SE	2	2
Regulation Number	-	21 CFR 892.2050	21 CFR 892.2050
Intended use	SE	Same	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.
Indications for use	SE		
Where used (hospital, home, ambulance, etc.)	SE	Same	Inside of hospitals, clinics, and physician's offices.
Application description	SE	Same	Sonix Health utilizes artificial intelligence to automate previous manual quantification tasks, resulting in increased efficiency for users. Our system performs view classification and measurements according to the US ASE guidelines, and the users can review and modify the results if necessary.
Semi-automated view classification	SE	PLAX LV, PLAX zoomed AV, PLAX zoomed MV, PLAX zoomed AV&MV, PLAX zoomed Aorta, A4C, A4C zoomed LV, A4C RV-focused, A2C, A2C zoomed LV, A3C, A3C zoomed LV, A5C, PSAX level of great vessels, PSAX level of MV, PSAX level of papillary muscles, PSAX level of apex, SC4C, SC long axis IVC, M-mode LA/Ao, M-mode LV, M-mode TAPSE, CW Doppler MS, CW Doppler MR, PW Doppler MV, CW Doppler AV in parasternal, CW Doppler AV, CW Doppler AR, CW Doppler TR, CW Doppler PV, CW Doppler PR, PW Doppler RVOT, PW Doppler LVOT, Mitral annulus TDI septal, Mitral annulus TDI lateral, Tricuspid annulus TDI lateral	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

Description	Decision	Subject Device (K240645)	Predicate Device (K230209)
Semi-automated measurements	SE	**[B-Mode]** IVSd (2D), IVSs (2D), LVIDd (2D), LVIDs (2D), LVPWd (2D), LVPWs (2D), Ao (2D), LA (2D), RVOT (2D), LVOT (2D), EF(Teich) (2D), RWT (2D), LAESV A4C, LVESV A4C, LVEDV A4C, LVGLS / LVSLS A4C, LARS A4C, LACtS A4C, LVEF MOD A4C, SV MOD A4C, RVEDA A4C, RVESA A4C, RVD1 A4C, RVD2 A4C, RVD3 A4C, RVFWS A4C, RV FAC A4C, LVESV A2C, LVEDV A2C, LAESV A2C, LVGLS/ LVSLS A2C, LVEF MOD A2C, LVGLS / LVSLS A3C **[M-Mode]** LAd (M), LAs (M), Aod (M), Aos (M), IVSd (M), IVSs (M), LVIDd (M), LVIDs (M), LVPWd (M), LVPWs (M), EF(Teich) (M), RWT(Teich) (M), SV(Teich) (M), LVEDV(Teich) (M), LVESV(Teich) (M), LVd Mass(ASE) (M), %FS (M), RV TAPSE (M) **[Doppler]** MS Vmax, MS VTI, MS PHT, MR Vmax, MR VTI, MV Peak E Vel, MV Peak A Vel, MV DecT, AV Vmax, AV VTI, PV Vmax, PV VTI, AR Vmax, AR PHT, PR Vmax, PR EDV, TR Vmax, TR VTI, RVOT Vmax, RVOT VTI, RVOT AccT, LVOT Vmax, LVOT VTI, E' Sept, A' Sept, S' Sept, E' Lat, A' Lat, S' Lat(Mitral), S' Lat (Tricuspid)	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 (mmode), 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)
Semi-automation technology	SE	Same	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.

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

8. Non-Clinical and Standalone 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 Basic Level of Documentation. 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).

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. The ground truth for strain measurements was established by the experts with the help of the reference devices (EchoPAC for global longitudinal, segmental and RV free wall strain and TOMTEC Arena for LA reservoir and contraction strain.

The results of the performance testing for additional features in this version are as follows. All other conditions are the same as the existing version (K230209).

We utilized heart images from 335 patients, taken for diagnostic purposes in actual clinical settings, to evaluate the performance of Sonix Health's Auto-Measure and Auto-Strain software. The test images were acquired following the IRB procedures. 303 patients were American, with images source from Mayo Clinic in Arizona, and Severance Hospital, Seoul, South Korea. Among them, 30% (93 patients) of the patients originated from U.S. hospitals, while 70% (200 patients) came from Korean hospital. 32 (32/335 = 10%) patients were obtained from South Korean with images source from Severance Hospital, Seoul, South Korea.

Sonix Health software was designed to assist clinicians in adult heart measurements. Three functions of Sonix Health software are the ‘View Recognition’, ‘Auto Measure’ and ‘Auto Strain’. This performance test report has described the performance test procedures and the result for novel features of the ‘Auto Measure’ and ‘Auto Strain’ software. Additionally, the previously approved 'View Recognition' feature demonstrates that it works well for additional views as well. A total of 335 patients’ images were used for performance validation, of which 303 (90%) were American and 32 (10%) were Korean.

The test showed that Sonix Health software successfully passed all categories of evaluation: it achieved an average accuracy of 96.25% for the additional views in the ‘View Recognition’ software (exceeding the acceptable threshold of 84%) and an average correlation coefficient of 0.918 (above the acceptable threshold of 0.80) when compared to manual measurements made by participating experts for ‘Auto Measure’. For the ‘Auto Strain’, it attained an average correlation coefficient of 0.88 for LVGLS values and LARS and LACts, surpassing the acceptable threshold of 0.80 when compared to manual measurements made by participating experts. And it

attained a correlation coefficient 0.69 of RV Free wall strain surpassing the acceptable threshold of 0.60 when compared to manual measurements made by participating experts. Additionally, it demonstrated an RMSE of 2.16 % for average GLS, staying below the acceptable threshold of 3.00. For Segmental Longitudinal Strain, the RMSE was 6.32%, also below the acceptable threshold of 7.50%, compared to manual measurements. We also demonstrated the statistical agreement between Sonix Health's automated measurements and the experts' manual measurements by providing Bland-Altman plots for all measurements. This report also includes additional measurements (A4C RV-focused RV FAC; A4C: LVEF, SV; PLAX LV: EF, RWT; and M-mode: EF, SV, EDV, ESV, %FS, LVd Mass) derived as simple arithmetic statistics of measurements which are provided by Sonix Health. Detailed performance testing results and the associated subgroup analysis are reported in the labeling

Through verification and validation activities, Sonix Health is confirmed to meet all the design and performance requirements, demonstrating substantial equivalence to the predicate device.

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 and Sonix Health is substantially equivalent to the currently marketed predicate device.