BrightHeart
Christophe Gardella
CTO
7-11 boulevard Haussmann
Paris, 75009
France

May 7, 2025

Re: K243684
Trade/Device Name: BrightHeart View Classifier
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 25, 2025
Received: March 25, 2025

Dear Christophe Gardella:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Jessica Lamb, PhD
Assistant Director,
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DHT8B: Division of Radiological Imaging
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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)*
K243684

Device Name
BrightHeart View Classifier

Indications for Use *(Describe)*
The BrightHeart View Classifier device is intended to analyze fetal 2D ultrasound images and video clips using machine learning techniques to automatically detect standard views during fetal heart scanning.

The BrightHeart View Classifier device is intended to be used as an adjunct to the acquisition and interpretation of fetal anatomic ultrasound examinations at the second or third trimester of pregnancy performed with transabdominal probes.

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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1. SUBMITTER

Applicant:	BrightHeart 7-11 boulevard Haussmann Paris 75009, France
Contact:	Christophe Gardella Chief Technical Officer Tel. +0033686543950 Email. christophe@brightheart.fr
Submission Correspondent:	Christophe Gardella
Date Prepared:	May 5, 2025

2. DEVICE

Device Trade Name:	BrightHeart View Classifier
Device Common Name:	Fetal ultrasound view classifier
Classification Name	21 CFR §892.2050, Medical image management and processing system
Product Code(s):	QIH
Regulatory Class:	Class II

3. PREDICATE DEVICE

Predicate Device: Sonix Health [K230209]

Reference Device: HeartAssist feature in the Samsung V8 Diagnostic Ultrasound System, V7 Diagnostic Ultrasound System [K223387]

4. DEVICE DESCRIPTION

BrightHeart View Classifier is a cloud-based software-only device which uses artificial intelligence (AI) to detect standard views during fetal heart scanning in fetal ultrasound images and video clips.

BrightHeart View Classifier is intended to be used by qualified, trained healthcare professional personnel in a professional prenatal ultrasound (US) imaging environment (this includes sonographers, MFMs, OB/GYN, and Fetal surgeons), to help fetal ultrasound examination acquisition and interpretation of 2D grayscale ultrasound by providing automatic classification of video clips and images into standard views, by automatically extracting example frames of standard views from video clips, and by automatically assessing whether the documentation of

each standard view in video clips and images satisfies an acquisition protocol defined by the center. Annotated DICOM files generated by the device cannot be modified by the user.

5. Intended Use/Indications for Use

The BrightHeart View Classifier device is intended to analyze fetal ultrasound images and video clips using machine learning techniques to automatically detect standard views during fetal heart scanning.

The BrightHeart View Classifier device is intended to be used as an adjunct to the acquisition and interpretation of fetal anatomic ultrasound examinations at the second or third trimester of pregnancy performed with transabdominal probes.

6. Substantial Equivalence

Technological Comparisons

The table below compares the key technological features of the subject device to the predicate device, Sonix Health.

Technological Comparison:

	Subject Device BrightHeart View Classifier	**Predicate Device** Sonix Health	**Reference Device** HeartAssist feature in the Samsung V8 Diagnostic Ultrasound System, V7 Diagnostic Ultrasound System.
510(k) Number	TBD	K230209	K223387
Applicant	BrightHeart	Ontact Health	Samsung
Classification Regulation	21 CFR §892.2050	21 CFR §892.2050	21 CFR §892.2150 21 CFR §892.1560 21 CFR §892.1570
Product Code	QIH	QIH, LLZ	IYN, IYO, ITX
Device Type	SaMD	SaMD	SaMD
Software algorithm	Machine Learning Model	Machine Learning Model	Machine Learning Model

	Subject Device BrightHeart View Classifier	**Predicate Device** Sonix Health	**Reference Device** HeartAssist feature in the Samsung V8 Diagnostic Ultrasound System, V7 Diagnostic Ultrasound System.
Imaging Modality	Fetal Ultrasound	Adult Echocardiography	The Samsung V8 and V7 are general purpose, mobile, software controlled, diagnostic ultrasound systems, including fetal ultrasound.
Model Inputs	Ultrasound images and video clips	Ultrasound images and video clips	Ultrasound images
Model method	Neural networks	Neural networks	Neural networks
Model trained to identify	Classification of ultrasound images into standard views of fetal heart.	Classification of ultrasound images into standard views of adult heart, determination cardiac measurements.	Classification of ultrasound images into standard views of fetal heart scanning, and detection of calipers used for measurements
Model Output	Identifies standard views of the heart and abdomen in images and video clips.	Identifies standard views of the heart in images and video clips, detection of cardiac measurements.	Identifies standard views of the heart and abdomen in images
PCCP	Included	Not included	Not included

The BrightHeart View Classifier and Sonix Health devices differ in that the BrightHeart View Classifier device uses as input fetal ultrasounds, whereas the Sonix Health device uses as input adult echocardiograms. The PCCP in the subject device includes proposed modifications related to modification of training and/or validation datasets, modification of data input sources regarding ultrasound machine make, addition of standard view, and modification of data input sources regarding gestational age.

The subject BrightHeart View Classifier and the predicate Sonix Health devices are both intended to be used to analyze ultrasound images to determine standard views during heart scanning. Both the subject and the predicate are Software as a Medical device (SaMD) applications that rely on a trained neural network to identify the standard views. The Sonix Health device also includes a measurement functionality which is not included in the BrightHeart

device. Both devices are intended to be used as an adjunct to professional decision-making by trained healthcare providers.

Similarities of the device with the predicate are maintained following PCCP modifications, and PCCP modifications do not incur additional differences with the predicate device.

In summary, the subject and predicate devices share the same fundamental technological characteristics, namely the use of software to assist healthcare professionals who are interpreting ultrasound images of the heart to determine standard views. The differences in implementations described above do not raise different questions of safety and effectiveness, so the Sonix Health device can be used as a predicate device for the BrightHeart View Classifier device.

7. Performance Data

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." and in accordance with IEC 62304:2016, *Medical device software - Software life cycle processes*.

Cybersecurity documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*".

Bench Testing

The following bench testing was performed to demonstrate substantial equivalence:

The device performance for standard view classification was validated with a dataset of 2290 clinically acquired images and frames from video clips from 579 fetal ultrasound examinations, performed with transabdominal probes at 18 weeks of gestation or later, from 8 centers.

Demographic distribution:

- gender: female
- age: 18 years or older
- ethnicity/country: U.S.A. and France.

Information about how the reference standard was derived from the dataset:

- The reference standard was derived from the dataset through a truthing process in which a sonographer and an MFM specialist with experience in fetal echocardiography determined the presence or absence of standard views on fetal ultrasound images.
- The truthing process was conducted independently of the BrightHeart View Classifier device.

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

- The ultrasound examinations used for training and validation are entirely distinct from the examinations used in performance testing.

The performance testing demonstrated that BrightHeart View Classifier identifies standard views with a mean standard view recognition sensitivity of 0.939 (95% CI, 0.917 ; 0.960) and a mean standard view recognition specificity of 0.984 (95% CI, 0.973 ; 0.996).

Stratified analysis by geographical region, by ultrasound machine make, by gestational age, by mother's BMI, and age, and by record type indicated that performance was consistent across subgroups, while analysis by mother's race showed that the specificity 95% CI lower bound was slightly lower for Asian and Black mothers, possibly due to large confidence intervals and small sample size.

BrightHeart View Classifier was validated only with General Electric, Philips, Samsung and Siemens ultrasound devices and is intended only to be used with these ultrasound vendors.

BrightHeart View Classifier was validated with pregnancies at 18 weeks of gestation or later recorded with transabdominal probes and is intended to be used only for such examinations.

8. Predetermined Change Control Plan

The BrightHeart View Classifier device is powered by a neural network performing standard view classification in fetal ultrasound images.

Modifications to the BrightHeart View Classifier device will be made in accordance with its Predetermined Change Control Plan (PCCP). The PCCP provides a description of the device's planned modifications, as well as procedures to implement, evaluate and deploy the modifications. These procedures ensure the continued safety and effectiveness of the device, mitigating risks associated with modifications to the BrightHeart View Classifier neural network to not adversely impact the device's performance, safety, or effectiveness associated with its indications for use, and an impact assessment of the planned modifications.

A summary of the planned modifications is provided in the table below. In line with the PCCP, all changes to the BrightHeart View Classifier will undergo development, evaluation and validation before release. Information on the deployment and post market surveillance of the algorithm are also provided for the proposed changes. Implemented modifications to the BrightHeart View Classifier will be communicated to users by email with a release note detailing all expected changes in the new release and user manual.

Summary of changes to BrightHeart View Classifier per the PCCP:

Modification	Rationale	Testing Methods	Impact Assessment

Modification of training and/or validation datasets to update model weights and detection thresholds	Improvements in the view classification performance of the device.	Re-training of the BrightHeart View Classifier with new data to optimize its performance followed by performance testing and a comparison of the original BrightHeart View Classifier to the modified BrightHeart View Classifier (using performance metrics) and verification and validation.	Improved performance metrics of modified BrightHeart View Classifier Benefit-Risk Analysis: Benefits: Improved performance; generalization for diverse cases. Risks: Overfitting; unintended bias. Risk Mitigation: Testing data sequestration and testing on new data will ensure proper evaluation and mitigate risks of overfitting.

Modification of data input sources: ultrasound machine make (Canon, Fujifilm, SIUI)	Improvement in the view classification performance with ultrasound machine makes not previously validated	Re-training of the BrightHeart View Classifier with data from new ultrasound machine makes to optimize its performance followed by performance testing and a comparison of the original BrightHeart View Classifier to the modified BrightHeart View Classifier (using performance metrics) and verification and validation.	Improved performance metrics of modified BrightHeart View Classifier on new ultrasound make <u>Benefit-Risk Analysis:</u> Benefits: Improved performance; generalization for diverse cases. Risks: Overfitting; unintended bias. <u>Risk Mitigation:</u> Testing data sequestration and testing on new data will ensure proper evaluation and mitigate risks of overfitting.

Addition of standard views (short-axis view at the level of the ventricles and short-axis view at the level of the atrioventricular valves)	Training of the machine learning model to achieve sufficient view classification performance for additional standard views, which will assist users in the identification of these views during fetal heart ultrasound scanning.	Re-training of the BrightHeart View Classifier with data from new standard views to optimize its performance followed by performance testing and a comparison of the original BrightHeart View Classifier to the modified BrightHeart View Classifier (using performance metrics) and verification and validation.	Improved performance metrics of modified BrightHeart View Classifier on additional standard views <u>Benefit-Risk Analysis:</u> Benefits: Improved performance; generalization for diverse cases. Risks: Overfitting; unintended bias. <u>Risk Mitigation:</u> Testing data sequestration and testing on new data will ensure proper evaluation and mitigate risks of overfitting.

Modification of data input sources: gestational age	Enables the device to achieve sufficient view classification performance to assist users in the identification of standard views for examinations corresponding to gestational ages not previously validated.	Re-training of the BrightHeart View Classifier with data from new gestational ages to optimize its performance followed by performance testing and a comparison of the original BrightHeart View Classifier to the modified BrightHeart View Classifier (using performance metrics) and verification and validation.	Improved performance metrics of modified BrightHeart View Classifier on new gestational age Benefit-Risk Analysis: Benefits: Improved performance; generalization for diverse cases. Risks: Overfitting; unintended bias. Risk Mitigation: Testing data sequestration and testing on new data will ensure proper evaluation and mitigate risks of overfitting.

9. CONCLUSION

The results of the testing described above demonstrate that the BrightHeart View Classifier is as safe and effective as the predicate device and supports a determination of substantial equivalence.