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

December 8, 2025

Re: K252294
Trade/Device Name: Fetal EchoScan (v1.2)
Regulation Number: 21 CFR 892.2060
Regulation Name: Radiological Computer-Assisted Diagnostic Software For Lesions Suspicious Of Cancer
Regulatory Class: Class II
Product Code: POK
Dated: November 13, 2025
Received: November 13, 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.

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, Ph.D.
Assistant Director
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)*

K252294

Device Name

Fetal EchoScan (v1.2)

Indications for Use *(Describe)*

Fetal EchoScan is a machine learning-based computer-assisted diagnosis (CADx) software device indicated as an adjunct to fetal heart ultrasound examination in pregnant women aged 18 or older undergoing second-trimester anatomic ultrasound exams.

When utilized by an interpreting physician, Fetal EchoScan provides information regarding the presence of any of the following suspicious radiographic findings:
- overriding artery
- septal defect at the cardiac crux
- abnormal relationship of the outflow tracts
- enlarged cardiothoracic ratio
- right ventricular to left ventricular size discrepancy
- tricuspid valve to mitral valve annular size discrepancy
- pulmonary valve to aortic valve annular size discrepancy
- cardiac axis deviation

Fetal EchoScan is to be used with cardiac fetal ultrasound video clips containing interpretable 4-chamber, left ventricular outflow tract, right ventricular outflow tract standard views.

Fetal EchoScan is intended for use as a concurrent reading aid for interpreting physicians. It does not replace the role of the physician or of other diagnostic testing in the standard of care. When utilized by an interpreting physician, this device provides information that may be useful in rendering an accurate diagnosis regarding the potential presence of morphological abnormalities that might be suggestive of fetal congenital heart defects that may be useful in determining the need for additional exams.

Fetal EchoScan is not intended for use in multiple pregnancies, cases of fetal heterotaxy and postnatal ultrasound exams.

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.

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:	December 8, 2025

2. DEVICE

Device Trade Name:	Fetal EchoScan (v1.2)
Device Common Name:	Medical image analyzer
Classification Name	Radiological computer-assisted diagnostic software for lesions suspicious for cancer 21 CFR 892.2060
Regulatory Class:	Class II
Product Code:	POK

3. PREDICATE DEVICE

Predicate Device: Fetal EchoScan (v1.1) [K251071].

4. DEVICE DESCRIPTION

Fetal EchoScan is a cloud-based software-only device which uses neural networks to detect suspicious cardiac radiographic findings for further review by trained and qualified physicians. Fetal EchoScan is intended to be used as an adjunct to the interpretation of the second-trimester fetal anatomic ultrasound exam performed between 18 and 24 weeks of gestation, for pregnant women aged 18 or more.

5. INTENDED USE/INDICATIONS FOR USE

Fetal EchoScan is a machine learning-based computer-assisted diagnosis (CADx) software device indicated as an adjunct to fetal heart ultrasound examination in pregnant women aged 18 or older undergoing second-trimester anatomic ultrasound exams.

When utilized by an interpreting physician, Fetal EchoScan provides information regarding the presence of any of the following suspicious radiographic findings:

- overriding artery
- septal defect at the cardiac crux
- abnormal relationship of the outflow tracts
- enlarged cardiothoracic ratio
- right ventricular to left ventricular size discrepancy
- tricuspid valve to mitral valve annular size discrepancy
- pulmonary valve to aortic valve annular size discrepancy
- cardiac axis deviation

Fetal EchoScan is to be used with cardiac fetal ultrasound video clips containing interpretable 4-chamber, left ventricular outflow tract, right ventricular outflow tract standard views.

Fetal EchoScan is intended for use as a concurrent reading aid for interpreting physicians. It does not replace the role of the physician or of other diagnostic testing in the standard of care. When utilized by an interpreting physician, this device provides information that may be useful in rendering an accurate diagnosis regarding the potential presence of morphological abnormalities that might be suggestive of fetal congenital heart defects that may be useful in determining the need for additional exams.

Fetal EchoScan is not intended for use in multiple pregnancies, cases of heterotaxy and postnatal ultrasound exams.

6. Substantial Equivalence

Technological Comparisons

The table below compares the key technological features of the subject devices to the predicate device.

Table 1. Device Comparison Table

	Subject Device Fetal EchoScan v1.2	**Predicate Device** Fetal EchoScan v1.1
510(k) Number	K252294	K242342
Applicant	BrightHeart	BrightHeart
Classification Regulation	892.2060	892.2060
Product Code	POK	POK
Device Type	SaMD	SaMD
Software algorithm	Machine Learning Model	Machine Learning Model
Imaging Modality	Fetal Ultrasound	Fetal Ultrasound

	Subject Device Fetal EchoScan v1.2	**Predicate Device** Fetal EchoScan v1.1
Model Inputs	Fetal ultrasound studies containing the following views in recordings: 4 chamber, left ventricular outflow tract, right ventricular outflow tract	Fetal ultrasound recordings containing the following views: 4 chamber, left ventricular outflow tract, right ventricular outflow tract
Model method	Suspicious radiographic findings categorized into 2 groups: ● "classification" features are based on the identification of morphological features within the video clip. ● "measurement" features are based on the detection and segmentation of key anatomic points	Suspicious radiographic findings categorized into 2 groups: ● "classification" features are based on the identification of morphological features within the video clip. ● "measurement" features are based on the detection and segmentation of key anatomic points
Model trained to identify	Video clips featuring the fetal heart. Identifiable suspicious radiographic findings of the fetal heart: ● overriding artery ● septal defect at the cardiac crux ● abnormal relationship of the outflow tracts ● enlarged cardiothoracic ratio ● right ventricular to left ventricular size discrepancy ● tricuspid valve to mitral valve annular size discrepancy ● pulmonary valve to aortic valve annular size discrepancy ● cardiac axis deviation	Identifiable suspicious radiographic findings of the fetal heart ● overriding artery ● septal defect at the cardiac crux ● abnormal relationship of the outflow tracts ● enlarged cardiothoracic ratio ● right ventricular to left ventricular size discrepancy ● tricuspid valve to mitral valve annular size discrepancy ● pulmonary valve to aortic valve annular size discrepancy ● cardiac axis deviation
Model Output	For each frame the software evaluates whether the findings are: present, absent, or inconclusive. An "exam summary table" displays a summary of the results for the overall study.	For each frame the software evaluates whether the findings are: present, absent, or inconclusive. A "record summary table" displays a summary of results for each video clip. An "exam summary table" displays a summary of the results for the overall study.
Output Display	● Annotated DICOMs within the user PACS viewer ● third-party user interface	● Annotated DICOMs within the user PACS viewer ● Device web interface

Discussion of Similarities and Differences

The Fetal EchoScan v1.2 subject device and Fetal EchoScan v1.1 predicate device differ in that the outputs of the predicate device are annotated DICOM files displayed in a DICOM viewer and may optionally be displayed on the device web interface, while the outputs of the subject device are annotated DICOM files displayed in a DICOM viewer and may optionally be displayed on a validated 3rd party user interface. The Fetal EchoScan outputs displayed on a user interface use a similar output presentation compared to the device annotated DICOMs.

The subject and predicate devices share the same fundamental technological characteristics, namely the use of software to assist physicians who are interpreting ultrasound images in making a diagnosis of the fetal heart and share the exact same algorithm to identify suspicious radiographic findings in the fetal heart.

In summary, the differences in implementations described above do not raise different questions of safety and effectiveness, so the Fetal EchoScan v1.1 device can be used as a predicate device for the Fetal EchoScan v1.2 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 and testing was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*".

Bench Testing

Standalone testing

The device performance for identification of suspicious radiographic findings was validated with a dataset of 877 clinically acquired fetal ultrasound exams during the 2nd trimester of pregnancy (18 to 24 weeks of gestational age), from 11 centers. Each exam consisted of all images and video clips recorded during the examination.

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 three pediatric cardiologists assessed the presence or absence of each of the eight findings, and majority voting was used.
- The truthing process was conducted independently of the Fetal EchoScan 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 standalone testing.

The subject device was evaluated based on 2 different scenarios:

- One where all inconclusive device outputs are counted as negative. This corresponds to a "worst-case scenario" for sensitivity (all Inconclusive exams which are Positive for the ground truth are counted as False Negative), and a "best-case scenario" for specificity (all Inconclusive exams which are Negative for the ground truth are counted as True Negative).
- One where all inconclusive device outputs are counted as positive. This corresponds to a "worst-case scenario" for specificity (all Inconclusive exams which are Negative for the ground truth are counted as False Positive), and a "best-case scenario" for sensitivity (all Inconclusive exams which are Positive for the ground truth are counted as True Positive).

The AI system had a conclusive output regarding the presence of any finding for 99.0% (95% CI, 98.1 ; 99.5) of exams. The standalone testing demonstrated that Fetal EchoScan detects suspicious findings with high sensitivity and high specificity, as shown in Table 1.

Table 1. Sensitivity and Specificity (with 95% CI) of Fetal EchoScan for the detection of any suspicious radiographic finding and of each suspicious radiographic finding.

Note: Specificity for each suspicious radiographic finding is computed on exams negative to all findings according to the ground truth (i.e., excluding exams negative to the analyzed finding but possibly positive to other findings).

	Inconclusive Exams Counted as Negative		**Inconclusive Exams Counted as Positive**	
	Sensitivity (Worst-Case)	**Specificity (Best-Case)**	**Sensitivity (Best-Case)**	**Specificity (Worst-Case)**
Any suspicious findings	0.984 (0.963 ; 0.993)	0.970 (0.952 ; 0.981)	0.990 (0.972 ; 0.997)	0.958 (0.938 ; 0.971)
Overriding artery	0.933 (0.868 ; 0.967)	0.988 (0.975 ; 0.994)	0.942 (0.880 ; 0.973)	0.979 (0.963 ; 0.988)
Cardiac crux septal defect	0.917 (0.838 ; 0.959)	0.995 (0.985 ; 0.998)	0.917 (0.838 ; 0.959)	0.995 (0.985 ; 0.998)
Abn. OT relationship	0.869 (0.781 ; 0.925)	0.988 (0.975 ; 0.994)	0.952 (0.884 ; 0.981)	0.982 (0.968 ; 0.990)
Enlarged CTR	0.955 (0.876 ; 0.985)	0.996 (0.987 ; 0.999)	0.955 (0.876 ; 0.985)	0.996 (0.987 ; 0.999)
Cardiac axis deviation	0.945 (0.851 ; 0.981)	1.000 (0.993 ; 1.000)	0.964 (0.877 ; 0.990)	1.000 (0.993 ; 1.000)
PV/AV size discrepancy	0.959 (0.921 ; 0.979)	0.986 (0.972 ; 0.993)	0.959 (0.921 ; 0.979)	0.986 (0.972 ; 0.993)
RV/LV size discrepancy	0.950 (0.900 ; 0.975)	1.000 (0.993 ; 1.000)	0.950 (0.900 ; 0.975)	1.000 (0.993 ; 1.000)

	Inconclusive Exams Counted as Negative		Inconclusive Exams Counted as Positive	
	Sensitivity (Worst-Case)	**Specificity (Best-Case)**	**Sensitivity (Best-Case)**	**Specificity (Worst-Case)**
TV/MV size discrepancy	0.950 (0.904 ; 0.974)	1.000 (0.993 ; 1.000)	0.950 (0.904 ; 0.974)	1.000 (0.993 ; 1.000)

Stratified analysis by gestational age, by mother's age, BMI and race, by ultrasound machine make and model and by image quality indicated that performance was consistent across subgroups.

Reader study

The predicate and subject devices share similar device output displays and similar algorithms, resulting in minor variations of device performance, as presented above. Therefore, bench testing for the predicate device remains valid for the subject device. We remind here the corresponding Reader study results:

Clinical performance of Fetal EchoScan was evaluated in a fully-crossed, multiple-reader multiple-case (MRMC) study, in which 14 readers reviewed 200 exams (18 to 24 weeks of gestational age). Readings were done in a randomized order, aided by Fetal EchoScan and unaided, with a 30 days washout period between both readings. Each exam consisted of all images and video clips recorded during the examination.

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 three pediatric cardiologists assessed the presence or absence of each of the eight findings, and majority voting was used.
- The truthing process was conducted independently of the Fetal EchoScan 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 standalone testing.

Table 2 and Figure 1 present reader performance when unaided and when aided by the device for identification of any suspicious radiographic finding and for each suspicious radiographic finding. The study results indicate that reviews by interpreting physicians were more accurate when aided by the Fetal EchoScan device compared to when unaided:

- The ROC AUC for detection of any suspicious radiographic finding was significantly higher in the aided compared to the unaided reading condition (see Figure 1): 0.974 (95%

CI 0.957-0.990) vs 0.825 (0.741-0.908), p=0.002 (using the Dorfman-Berbaum-Metz and Obuchowski-Rockette method): **+14.9% increase in AUC**.

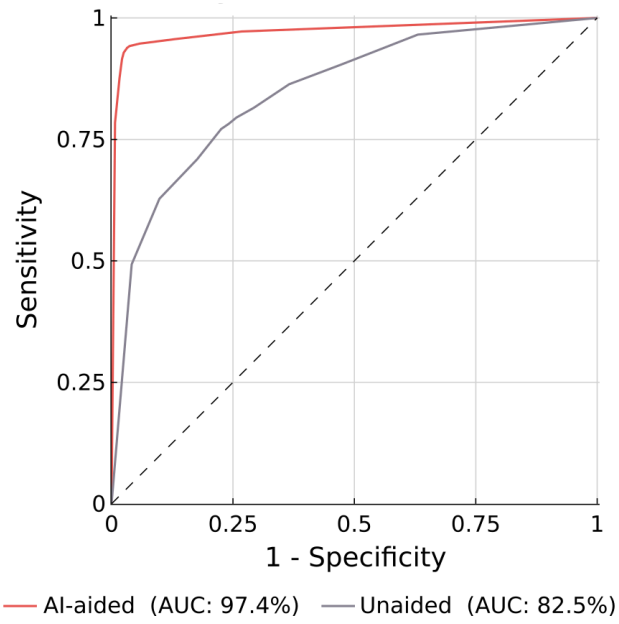
- The mean sensitivity for identification of any claimed suspicious finding was 0.935 (0.892-0.978) in the aided reading condition vs 0.782 (0.686-0.878) in the unaided reading condition: **+15.3% increase in sensitivity**.
- The mean specificity for identification of any claimed suspicious finding was 0.970 (0.949-0.991) in the aided reading condition vs 0.759 (0.630-0.887) in the unaided reading condition: **+21.1% increase in specificity**.

Table 2. Empirical ROC AUC Analysis by Suspicious Radiographic Finding

Note: Per-finding AUC is based on specificity computed excluding exams negative to the analyzed finding but possibly positive to other findings.

	Aided	Unaided	Aided minus Unaided	
	Model Estimate AUC (95% CI)	Model Estimate AUC (95% CI)	Model Estimate Difference (95% CI)	DBM-OR p-value
Any suspicious findings	0.974 (0.957 ; 0.990)	0.825 (0.741 ; 0.908)	0.149 (0.066 ; 0.232)	0.002
Overriding artery	0.953 (0.916 ; 0.990)	0.803 (0.719 ; 0.888)	0.150 (0.063 ; 0.237)	0.002
Cardiac crux septal defect	0.971 (0.943 ; 0.999)	0.857 (0.782 ; 0.933)	0.114 (0.042 ; 0.186)	0.004
Abn. OT relationship	0.972 (0.953 ; 0.992)	0.832 (0.738 ; 0.927)	0.140 (0.048 ; 0.232)	0.005
Enlarged CTR	0.960 (0.930 ; 0.989)	0.746 (0.666 ; 0.826)	0.214 (0.131 ; 0.297)	<0.001
Cardiac axis deviation	0.967 (0.932 ; 1.000)	0.786 (0.704 ; 0.867)	0.181 (0.106 ; 0.256)	<0.001
PV/AV size discrepancy	0.979 (0.962 ; 0.997)	0.839 (0.756 ; 0.921)	0.140 (0.060 ; 0.221)	0.002
RV/LV size discrepancy	0.991 (0.983 ; 0.999)	0.868 (0.801 ; 0.936)	0.123 (0.055 ; 0.190)	0.001
TV/MV size discrepancy	0.964 (0.938 ; 0.990)	0.850 (0.779 ; 0.921)	0.114 (0.048 ; 0.179)	0.002

Figure 1. ROC AUC analysis for detection of any suspicious radiographic finding by OB-GYNs and MFMs in aided and unaided conditions.



Stratified analysis by gestational age, by mother's age, BMI and race, by ultrasound machine make and model, image quality, reader specialty, reader country of practice and for each suspicious finding indicated that performance was consistent across subgroups.

Fetal EchoScan was validated only with Fujifilm, GE, Philips, Samsung and Toshiba ultrasound devices and is intended only to be used with these ultrasound vendors.

8. Conclusion

The results of the testing described above demonstrate that the Fetal EchoScan v1.2 is as safe and effective as the predicate device and supports a determination of substantial equivalence.