July 25, 2023

Sonio
% Florian Akpakpa
Head of Regulatory Affairs and Quality Assurance
24 Rue du Faubourg Saint Jacques
Paris, FR-75014
FRANCE

Re: K230365
Trade/Device Name: Sonio Detect
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, QIH
Dated: June 26, 2023
Received: June 27, 2023

Dear Florian Akpakpa:

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
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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.

Submission Number *(if known)*

K230365

Device Name

Sonio Detect

Indications for Use *(Describe)*

Sonio Detect is intended to analyze fetal ultrasound images and clips using machine learning techniques to automatically detect views, detect anatomical structures within the views and verify quality criteria of the views.

The device is intended for use as a concurrent reading aid during the acquisition and interpretation of fetal ultrasound images.

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.

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K230365

510(k) Summary

In accordance with 21 CFR 807.92 the 510(k) summary for Sonio Detect is provided below.

I. Submitter

Applicant:	Sonio 24 rue du Faubourg Saint Jacques, 75014, Paris France
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Date Prepared:	July 25, 2023

II. Device

Device Trade Name:	Sonio Detect
Classification Name:	21 CFR 892.1550 - accessory to Ultrasonic Pulsed Doppler Imaging System 21 CFR 892.1560 - accessory to Ultrasonic Pulsed Echo Imaging System 21 CFR 892.2050 - Medical image management and processing system
Regulatory Class:	Class II
Product Codes:	IYN (Primary) IYO, QIH (Secondary)

III. Predicate Device

SonoLyst feature embedded in the GE Medical device Voluson SWIFT, K201828.

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description

Sonio Detect is a Software as a Service SaaS solution that aims at helping sonographers, OB/GYNs, MFMs and Fetal surgeons (all three designated as healthcare professionals i.e. HCP) to perform their routine fetal ultrasound examinations in real-time. Sonio Detect can be used by Healthcare Professionals HCPs during fetal ultrasound exams for Trimester 1, Trimester 2 and Trimester 3 of the fetus (Gestational Age: from 11 weeks to 37 weeks). The software is intended to assist HCPs in assuring during and after their examination that the examination is complete and all images were collected according to their protocol.

Sonio Detect requires the following:

- Edge Software (described below) to install on a server on the same network as the Ultrasound Machine;
- SaaS accessibility from internet browser.

Sonio's Edge Software is a light-weight application that runs on a server (computer) connected to the same network as the Ultrasound Machine. Sonio Edge Software is installed on the HCP server (computer) and network and the main purpose is to receive DICOM instances from the Ultrasound Machine and upload them to Sonio's Cloud to be used by Sonio Detect.

Sonio Detect receives fetal ultrasound images and clips from the ultrasound machine, that are submitted through the edge software by the performing healthcare professional, in real-time and performs the following:

- Automatically detect views;
- Automatically detect anatomical structures within the supported views;
- Automatically verify quality criteria of the supported views by checking whether they conform to standardized quality criteria.

Quality criteria are related to:

- the presence or absence of an anatomical structure;
- the zoom level for some views.

Sonio Detect then automatically associates the image to its detected view. It also highlights in yellow the view and/or the corresponding quality criteria if there are unverified items : quality criteria not verified or view not detected.

The end user can interact with the software to override the Sonio Detect's outputs (reassign the image to another view or unassign it or assign it if it was not assigned, change the status of a

quality criteria from verified to unverified or from unverified to verified). The user has the ability to review and edit/override the matching at any time during or at the end of the exam.

The list of views, anatomical structures and quality criteria that can be automatically detected and verified by the software are detailed in the tables 1, 2 and 3 below.

Table 1: List of views that can be automatically detected by the software

View	Gestational Age of the fetus
Transthalamic or Cavum septum Pellucidum or Midline falx / Transventricular or Choroid plexus	T1 and T2/T3
Profile or Nuchal translucency	T1 and T2/T3
Crown rump length	T1
Sagittal spine	T2/T3
Abdominal circumference	T2/T3
Long bone	T2/T3
Transcerebellar view	T2/T3
Upper lip, nose and nostrils	T2/T3
Four chambers	T2/T3
Left ventricular outflow tract	T2/T3
Right ventricular outflow tract	T2/T3

Table 2:List of anatomical structures that can be automatically detected by the software

View	Structure
Brain views and structures at T2/T3	
Transthalamic view Transventricular view Transcerebellar view	• Midline falx • Cavum septum pellucidum • Cerebellum
Heart views and structures at T2/T3	
Four Chambers Three vessels LVOT	• Aorta • Apex heart • Ascending aorta • Descending aorta • Interatrial septum • Interventricular septum • Left atrium • Left ventricle • Pulmonary trunk • Right atrium • Right ventricle • Superior vena cava

Table 3: List of quality criteria that can be automatically verified by the software

Quality criteria of the brain views	
For the transthalamic view, Sonio Detect automatically evaluates the following criteria:	• Presence of the cavum septum pellucidum • Absence of the cerebellum • Brain occupies more than half of the width of the ultrasound image
For the transcerebellar view, Sonio Detect automatically evaluates the following criteria:	• Presence of the cerebellum • Presence of the cavum septum pellucidum • Brain occupies more than half of the width of the ultrasound image
For the transventricular view, Sonio Detect automatically evaluates the following criteria:	• Presence of the cavum septum pellucidum • Brain occupies more than half of the width of the ultrasound image
Quality criteria of the heart views	
For the 4 chambers view, Sonio Detect automatically evaluates the following criteria:	• Presence of the right ventricle • Presence of the left ventricle • Presence of the left atrium • Presence of the right atrium • Presence of the interventricular septum • Presence of the interauricular septum • Presence of the apex of the heart • Presence of the descending aorta
For the 3 vessels and 3 vessels and trachea views, Sonio Detect automatically evaluates the following criteria:	• Presence of the pulmonary trunk • Presence of the ascending aorta • Presence of the superior vena cava
For the LVOT view, Sonio Detect automatically evaluates the following criteria:	• Presence of the left ventricle • Presence of the aorta • Presence of the right ventricle • Presence of the left atrium • Presence of the apex of the heart

V. Indications for Use

Sonio Detect is intended to analyze fetal ultrasound images and clips using machine learning techniques to automatically detect views, detect anatomical structures within the views and verify quality criteria of the views.

The device is intended for use as a concurrent reading aid during the acquisition and interpretation of fetal ultrasound images.

Sonio Detect and the predicate device have the same intended use for automatic detection of views as well as automatic detection of anatomical structures within the views and verification of quality criteria of the views by comparing them to standardized quality criteria. The Indications for Use statement for Sonio Detect is not identical to the predicate device; however, the difference does not affect the safety and effectiveness of the device relative to the predicate, and so does not constitute a new intended use.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 4 provides a comparison of the Technological Characteristics of Sonio Detect to the predicate SonoLyst.

Table 4: Comparison of technological characteristics

Items	**Predicate device 1:** SonoLyst feature in Voluson SWIFT - K201828	**Proposed device:** Sonio Detect
Manufacturer name	GE Medical	Sonio
Device name	SonoLyst feature embedded in the device Voluson SWIFT	Sonio Detect
Regulation Number	- Ultrasonic Pulsed Doppler Imaging System. 21 CFR 892.1550, 90-IYN; -Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO; -Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX	- Accessory to Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550 - Accessory to Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560 - Medical image management and processing system, 21 CFR 892.2050
Product codes	IYN (primary) IYO ITX (secondary)	IYN (Primary) IYO, QIH (Secondary)
Clinical outcome	- Images labeled with correct view - Quality criteria are identified as “found” when detected and “not found” when not detected	- Images labeled with correct view - Quality criteria are identified as “Verified” when detected and “Not verified” when not detected

Items	**Predicate device 1:** SonoLyst feature in Voluson SWIFT - K201828	**Proposed device:** Sonio Detect
Intended Users	General purpose radiology evaluation and specialized for OB/GYN	Qualified and trained healthcare professional personnel in a professional prenatal ultrasound (US) imaging environment (this includes sonographers, MFMs, OB/GYN, and Fetal surgeons)
Clinical applications	Fetal/Obstetrics	Fetal/Obstetrics
Algorithm Methodology	Artificial Intelligence	Artificial Intelligence Lecture of biometrics Colorimetry for 3D and Doppler
Platform	Embedded in the ultrasound equipment	Secure cloud-based and stand-alone software compatible with ultrasound system from GE Medical, Samsung and Canon

Sonio Detect's intended users, clinical outcome and clinical applications are similar to those of the predicate device, SonoLyst.

Sonio Detect differ to SonoLyst in the following:

- Algorithm methodology: Sonio Detect algorithm technology is based on Artificial Intelligence, Lecture of biometrics on the image and Colorimetry identification for 3D and Doppler while the Predicate SonoLyst's algorithm technology is only based on Artificial Intelligence;
- Platform: Sonio Detect is a stand-alone cloud based software that can be used with different ultrasound systems while the Predicate SonoLyst is embedded in the GE ultrasound system.

However, the differences in algorithm methodology and platform do not raise different questions of safety and effectiveness of the device.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were 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."
The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Design Reviews
- Software Development Lifecycle
- Algorithm Verification (Algorithm internal validation)
- Software verification
- Simulated use testing (Validation)
- Performance testing (Verification)

Bench Testing
Sonio conducted a standalone performance testing on a dataset of 17885 fetal ultrasound images from 7 clinical sites in the United States, France and Germany representative of the intended use population. This dataset was independent of the data used during model development (training/fine tuning/internal validation) and establishment of device operating points.

The results of the standalone performance testing demonstrate that Sonio Detect:

- Automatically detects 3D fetal ultrasound images with high sensitivity (0,980; 95% Wilson's Confidence Interval: 0.930, 0.994) and Doppler fetal ultrasound images with high sensitivity (0,963; 95% Wilson's Confidence Interval: 0.908, 0.985);
- Automatically detects fetal ultrasound views through reading of annotations on images with high proportions of annotations read correctly (0,923; 95% Wilson's Confidence Interval: 0.905, 0.938);
- Automatically detects some T1 fetal ultrasound views with high sensitivity (0,942; Point estimate).
- Automatically detects some T2/T3 fetal ultrasound views with high sensitivity (0,919; Point estimate).
- Automatically detects some fetal brain anatomical structures in some T2/T3 brain views with high sensitivity (0,857; Point estimate) and high specificity (0,963; Point estimate), and so automatically verifies the corresponding quality criteria;
- Automatically detects some fetal heart anatomical structures in the some T2/T3 heart views with high sensitivity (0,900; Point estimate) and high specificity (0,982; Point estimate) and so automatically verifies the corresponding quality criteria.
- Automatically verifies the zoom level for some brain views with high sensitivity (0.952; 95% Wilson's Confidence Interval: 0.909-0.976) and high specificity (0.906; 95% Wilson's Confidence Interval: 0.758-0.968).

Additionally the performance was also validated for subgroups including: Ultrasound machine manufacturer, BMI, maternal age, gestational age and race and ethnicity when appropriate.

Sonio Detect was validated only with GE, Canon, and Samsung ultrasound devices and is intended only to be used with these ultrasound vendors.

The results of verification and performance testing demonstrate the safe and effective use of Sonio Detect.

Clinical Study
Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

VIII. Conclusions

Sonio Detect's intended users, clinical outcome and clinical applications are similar to those of the predicate device SonoLyst.
The technological characteristics differences identified and discussed in Section VI do not raise different questions of safety and effectiveness of the device.
Furthermore, results of successful verification and validation activities and additional bench performance testing do not raise any new issue regarding the safety and effectiveness of the device.
Thus, Sonio Detect is substantially equivalent to its predicate device SonoLyst (K201828).