April 26, 2024

Sonio
℅ Florian Akpakpa
Head of Quality Assurance and Regulatory Affairs
17 Rue du Faubourg Montmartre
Paris, 75009
FRANCE

Re: K240406
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: February 9, 2024
Received: February 9, 2024

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 (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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240406

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 and characteristics 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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510(k) Summary

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

I. Submitter

Applicant:	Sonio 17 Rue du Faubourg Montmartre, 75009, Paris France
Primary Contact Person:	Florian Akpakpa Head of Regulatory Affairs and Quality Assurance Sonio Phone: +33 6 19 38 71 45 Email: florian.akpakpa@sonio.ai
Date Prepared:	February 9th, 2024

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 Code:	IYN (primary) IYO, QIH (Secondary)

III. Predicate Device

Sonio Detect cleared in K230365.

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/GYN MFMs and Fetal surgeons (all three designated as healthcare professionals i.e. HCP in the following) 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 (GA: 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 any internet browser (recommended browser: Google Chrome).

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 and characteristics of the supported views by checking whether they conform to standardized quality criteria

Quality criteria are related to:

- The presence of an anatomical structure;
- The absence of an anatomical structure;

Characteristics are related to other items than quality criteria:

- Location of the placenta
- Fetus sex

Sonio Detect then automatically associates the image to its detected view. It also highlights in yellow the view and/or the corresponding quality criteria or characteristics if there are unverified items: quality criteria or characteristics 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, changes the status of a quality criteria from verified to unverified or from unverified to verified) and manually set the characteristics of the views. 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, quality criteria and characteristics that can be automatically detected and verified by the software are detailed in tables 1, 2, 3 and 4 below.

Table 1: List of views per trimester that can be automatically detected by Sonio Detect

Trimester	View
First Trimester	1. Transthalamic or Cavum septum pellucidum or Midline falx/Transventricular or Choroid Plexus 2. Profile/Nuchal translucency 3. 4 Chambers 4. Abdominal circumference 5. Hand 6. Foot 7. Crown Rump Length
Second and Third trimester	1. Transthalamic or Cavum septum pellucidum or Midline falx/Transventricular or Choroid Plexus 2. Transcerebellar view 3. Profile 4. Lips and Nose 5. Orbits 6. 4 Chambers 7. LVOT 8. RVOT 9. 3 vessels/3 vessels and trachea 10. Sagittal Spine 11. Abdominal circumference 12. Axial Bladder 13. Axial Kidneys 14. Long bone 15. Hand 16. Foot 17. External genitalia (female and male) 18. Placenta insertion

Table 2: List of anatomical structures that can be automatically detected by Sonio Detect

View name	Structures to be detected	First Trimester T1	Second/Third Trimester T2/T3
Brain views & structures			
Transthalamic view Transventricular view Transcerebellar view	Thalami on the transthalamic view	-	X
	Cavum septum pellucidum	-	X
	Pillars of the fornix	-	X
	Sylvian fissure	-	X
	Ventricle	-	X
	Choroid Plexus	-	X
	Cisterna Magna	-	X
	Cerebellum	-	X
Thorax and Heart views & structures			
4 chambers 3 vessels 3 vessels and trachea RVOT LVOT Abdominal circumference Axial view of the kidneys	Adrenal gland	-	X
	Apex of the heart	-	X
	Descending aorta	-	X
	Interatrial septum	-	X
	Interventricular septum	X	X
	Kidneys	-	X
	Left atrium	X	X
	Left ventricle	X	X
	Mitral valve	-	X
	Pulmonary vein	-	X
	Right atrium	X	X
	Right ventricle	X	X
	Stomach	X	X
	Superior vena cava	-	X
	Tricuspid valve	-	X
	Umbilical vein	-	X
	Ascending aorta on LVOT View	-	X
	Ascending aorta on RVOT or 3 vessels view	-	X
	Pulmonary artery trunk on 3 vessels View	-	X
	Pulmonary artery with visible bifurcation	-	X

View name	Structures to be detected	First Trimester T1	Second/Third Trimester T2/T3
CRL/NT/Profile/Corpus callosum views & structures			
CRL NT Profile Corpus Callosum	Nasal bone	X	X
	Diencephalon	X	-
	Fourth ventricle on NT view	X	-
	Nuchal translucency	X	-
	Palate	X	X
	Corpus Callosum	-	X
	Liquid space under the chin	X	-
	Midbrain tectum	-	X
	Vermis	-	X
	Choroid plexus on sagittal plane	-	X
	Cisterna magna on NT view	X	-
	Brainstem on NT view	X	-
Placenta view & structures			
Placenta insertion	Cervix	-	X
	Maternal bladder	-	X
	Internal cervical os	-	X
	Placenta	-	X

Table 3: List of quality criteria that can be automatically verified by Sonio Detect

View name	Quality criteria	First trimester T1	Second/Third Trimester T2/T3
Quality criteria of the brain views			
Transthalamic view	Presence of the cavum septum pellucidum or of the pillars of the fornix	-	X
	Presence of the cavum septum pellucidum	-	X
	Presence of the Sylvian fissure	-	X
	Absence of the cerebellum	-	X
	Presence of the thalami	-	X
Transventricular view	Presence of the ventricle	-	X
	Absence of the thalami	-	X
	Presence of the cavum septum pellucidum	-	X
Transcerebellar view	Presence of the cerebellum	-	X
	Presence of the cisterna Magna	-	X
	Presence of the cavum septum pellucidum	-	X
Quality criteria of the thorax and heart views			
4 chambers view	Presence of the Left ventricle	X	X
	Presence of the Right ventricle	X	X
	Presence of the Left atrium	X	X
	Presence of the Right atrium	X	X
	Presence of the interventricular septum	X	X
	Presence or the inter atrial septum	-	X
	Presence of the apex of the heart	-	X
	Presence of the mitral valve	-	X
	Presence of the tricuspid valve	-	X
	Presence of the descending aorta	-	X
	Presence of at least one pulmonary vein	-	X
3 vessels and 3 vessels and trachea views	Presence of the Pulmonary artery	-	X
	Presence of the ascending aorta	-	X
	Presence of the superior vena cava	-	X

View name	Quality criteria	First trimester T1	Second/Third Trimester T2/T3
LVOT view	Presence of the Left ventricle	-	X
	Presence of the Left atrium	-	X
	Presence of the ascending aorta	-	X
	Presence of the apex of the heart	-	X
	Presence of the right ventricle	-	X
	Presence of the interventricular septum	-	X
RVOT view	Presence of the pulmonary artery with visible bifurcation	-	X
	Presence of the right ventricle	-	X
	Presence of the ascending aorta	-	X
Abdominal circumference view	Presence of the stomach	X	X
	Presence of at least one adrenal gland	-	X
	Presence of the descending aorta	-	X
	Presence of the umbilical vein	-	X
	Absence of the kidneys	-	X
Axial view of the two kidneys	Presence of two kidneys	-	X
	Absence of the stomach	-	X
Quality criteria of CRL/NT/Profile/Corpus callosum views			
Nuchal Translucency view	Presence of the nasal bone	X	-
	Presence of the nuchal translucency	X	-
	Presence of the cisterna magna	X	-
	Presence of the fourth ventricle	X	-
	Presence of the Diencephalon	X	-
	Presence of the brainstem	X	-
	Presence of the palate	X	-
	Presence of liquid space under the chin	X	-
CRL view	Presence of the nasal bone	X	-
	Presence of liquid space under the chin	X	-
	Presence of the palate	X	-

View name	Quality criteria	First trimester T1	Second/Third Trimester T2/T3
Profile view	Presence of the palate	-	X
	Presence of the nasal bone	-	X
Corpus Callosum view	Presence of the corpus callosum	-	X
	Presence of the plexus choroid (third ventricle)	-	X
	Presence of the midbrain tectum	-	X
	Presence of the vermis	-	X
Quality criteria of Placenta view			
Placenta insertion	Presence of the internal cervical os	-	X
	Presence of the cervix	-	X
	Presence of the maternal bladder	-	X

Table 4 : List of characteristics that can be automatically verified by Sonio Detect

View name	Characteristics	First trimester T1	Second/Third Trimester T2/T3
Genitalia view	Male	-	X
	Female	-	X
Placenta location	Anterior	-	X
	Posterior	-	X

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 and characteristics 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 have similar intended use. Both devices are used as a concurrent aid to automatically detect fetal ultrasound views, automatically detect fetal anatomical structures within the views.

The indications for use of Sonio Detect v2 and the predicate differ in the characteristics verification. Sonio Detect v2 automatically verifies both the characteristics and quality criteria of the views whereas the predicate Sonio Detect only automatically verifies the quality criteria. However, these differences do not raise new questions regarding safety and effectiveness of the device when used as labeled.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 5 provides a comparison of the Technological Characteristics of Sonio Detect to the predicate Sonio Detect cleared in K230365.

Table 5: Comparison of technological characteristics

Items	Predicate device: Sonio Detect - K230365	Proposed device: Sonio Detect v2
Manufacturer name	Sonio	Sonio
Device name	Sonio Detect	Sonio Detect
Regulation Number	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	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
Product code	IYN (primary) IYO, QIH (Secondary)	IYN (primary) IYO, QIH (Secondary)
Features	- Sonio Detect automatically detects views - Sonio Detect automatically detects anatomical structures within the supported views - Sonio Detect automatically verifies the quality criteria of the supported views by checking whether they conform to standardized quality criteria.	- Sonio Detect automatically detects views - Sonio Detect automatically detects anatomical structures within the supported views - Sonio Detect automatically verifies the quality criteria and characteristics of the supported views.
Algorithm Methodology	Artificial Intelligence Lecture of biometrics Colorimetry for 3D and Doppler	Artificial Intelligence Lecture of biometrics Colorimetry for 3D and Doppler
Platform	Secure cloud-based and stand-alone software compatible with ultrasound system from GE Medical, Samsung and Canon	Secure cloud-based and stand-alone software compatible with ultrasound system from GE Medical, Samsung, Canon and Philips

Sonio Detect v2 and its predicate device, Sonio Detect, use the same algorithm methodology.

Sonio Detect v2 and its predicate differs in the following:

- the platform: Sonio Detect v2 and its predicate differ in their compatibility with ultrasound machine manufacturers. Both devices support ultrasound systems from GE Medical, Samsung and Canon. However, only Sonio Detect v2 is compatible with the ultrasound system from the manufacturer Philips.

However, these differences do not raise new questions regarding safety and effectiveness of the device when used as labeled.

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, "Content of Premarket Submissions for Device Software Functions."

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 units verification
- Software verification
- Simulated use testing (Validation)
- Performance testing
- Cybersecurity testing

Bench Testing

Sonio conducted a standalone performance testing on a dataset of 36 769 fetal ultrasound images. This global validation 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 demonstrated that Sonio Detect performs the following, as summarized in table below:

Table 6: results of the standalone performance testing

Items (fetal ultrasound views, anatomical structures and characteristics automatically detected)	Sensitivity		Specificity	
	Point Estimate	Wilson CI (95%)	Point Estimate	Wilson CI (95%)
Automatic detection of 3D fetal ultrasound images	0.892	(0.836-0.931)	-	-
Automatic detection of Doppler fetal ultrasound images	0.973	(0.937-0.988)	-	-
Automatic detection of fetal ultrasound views through reading of annotations on images	0.913	(0.852-0.951)	-	-
Automatic detection of 7 T1 fetal ultrasound images	0.914	(0.906-0.921)	-	-
Automatic detection of 18 T2/T3 fetal ultrasound images	0.937	(0.933-0.940)	-	-
Automatic detection of 8 fetal brain anatomical structures on the views “Transthalamic”, “Transventricular”, “Transcerebellar” at T2/T3	0.934	(0.925-0.943)	0.949	(0.942-0.955)
Automatic detection of 6 fetal thorax and heart anatomical structures on the views “Four chambers”, “LVOT”, “RVOT”, “Three vessels or Three vessels and trachea”, “Abdominal Circumference”, “Axial view of the kidneys” at T1	0.861	(0.841-0.878)	0.938	(0.926-0.948)
Automatic detection of 21 fetal thorax and heart anatomical structures on the views “Four chambers”, “LVOT”, “RVOT”, “Three vessels or Three vessels and trachea”, “Abdominal Circumference”, “Axial view of the kidneys” at T2/T3	0.919	(0.913-0.924)	0.976	(0.974-0.978)
Automatic detection of 4 fetal placenta anatomical structures on the views “Placenta insertion”, “Placenta location” at T2/T3	0.967	(0.955-0.975)	0.856	(0.838-0.871)

Items (fetal ultrasound views, anatomical structures and characteristics automatically detected)	Sensitivity		Specificity	
	Point Estimate	Wilson CI (95%)	Point Estimate	Wilson CI (95%)
Automatic detection of 8 fetal CRL/NT/Profile anatomical structures on the views "Crown Rump Length", "Nuchal Translucency", "Profile" at T1	0.898	(0.885-0.910)	0.862	(0.845-0.878)
Automatic detection of 6 fetal CRL/NT/Profile anatomical structures on the views "Crown Rump Length", "Nuchal Translucency", "Profile" at T2/T3	0.893	(0.879-0.906)	0.956	(0.949-0.962)
Automatic detection of the Anterior placenta location for the views "Placenta insertion", "Placenta location" at T2/T3	0.959	(0.918-0.980)	0.966	(0.924-0.986)
Automatic detection of the Posterior placenta location for the views "Placenta insertion", "Placenta location" at T2/T3	0.966	(0.924-0.986)	0.959	(0.918-0.980)
Automatic detection of the "Female sex" for fetal sex for the view "External Genitalia"	0.977	(0.942-0.991)	0.987	(0.963-0.996)
Automatic detection of the "Male sex" for fetal sex for the view "External Genitalia"	0.987	(0.963-0.996)	0.977	(0.942-0.991)

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

Sonio Detect was validated only with GE, Canon, Philips 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 Sonio Detect, the cleared version in K230365.
The technological characteristics differences identified and discussed in Section VI do not raise any 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 Sonio Detect (K230365).