



March 16, 2026

Sonio
Florian Akpakpa
Director of Regulatory Affairs and Compliance Officer
147 rue d'Aboukir
Paris, 750002
France

Re: K252433
Trade/Device Name: Sonio Detect (v3)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, QIH
Dated: February 14, 2026
Received: February 17, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
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Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252433

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Please provide the device trade name(s).

?

Sonio Detect (v3)

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

K252433

510(k) Summary

In accordance with 21 CFR 807.92 the 510(k) summary for Sonio Detect v3 is provided below.

I. Submitter

Applicant:	Sonio 147 rue d'Aboukir, 75002, Paris France
Primary Contact Person:	Florian Akpakpa Director Regulatory Affairs and Compliance Officer Sonio Phone: +33 6 66 66 19 89 Email: florian.akpakpa@sonio.ai
Date Prepared:	February 13, 2026

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 v2 cleared in K240406.

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 41 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
- Automatically output bounding box for views and structures

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

510(k) Premarket Notification Submission

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. Choroid Plexus 2. Profile/Nuchal translucency 3. Abdominal circumference 4. Hand 5. Foot 6. Crown Rump Length 7. Doppler 3VT 8. Lower Arm 9. Upper Leg 10. Lower Leg 11. Doppler 4CH 12. Adnexa 13. Ovaries 14. Umbilical cord insertion
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. Sagittal Spine 9. Abdominal circumference 10. Axial Bladder 11. Axial Kidneys 12. Cervix/Placenta 13. Hand 14. Foot 15. External genitalia (female or male) 16. 3 Vessels/3 Vessels and Trachea (3VV) 17. 3 Vessels and Trachea (3VT) 18. Doppler 3VT

Trimester	View
	19. Humerus 20. Femur 21. Radius/Cubitus 22. Tibia/Fibula 23. Upper arm 24. Lower arm 25. Upper leg 26. Adnexa 27. Ovaries 28. Placenta Cord Insertion 29. Coronal Face 30. Doppler 4CH 31. Umbilical Cord Insertion 32. Coronal Kidneys 33. Diaphragm 34. Maxilla 35. Mandible 36. Aortic Arch 37. Ductal Arch 38. Bicaudal View 39. Palate 40. Corpus Callosum

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 Trimesters T2/T3
Brain views & structures			
Transthalamic Transventricular Transcerebellar Choroid plexus	Thalami on the transthalamic view	X	X
	Cavum septum pellucidum	-	X
	Sylvian fissure	-	X
	Choroid Plexus	-	X
	Cisterna Magna	-	X
	Cerebellum	-	X
	Vermis	-	X
Thorax and Heart views & structures			
4 chambers 3VV 3VT RVOT LVOT Abdominal circumference Axial view of the kidneys Diaphragm Crown Rump length Abdominal cord insertion	Adrenal gland	-	-
	Apex of the heart	-	X
	Descending aorta	-	X
	Interatrial septum	-	X
	Interventricular septum	X	X
	Kidneys	-	-
	Left atrium	X	X
	Left ventricle	X	X
	Right atrium	-	X
	Right ventricle	-	X

View name	Structures to be detected	First Trimester T1	Second/Third Trimesters T2/T3
	Spine	-	-
	Stomach (axial / sagittal)	X	X
	Superior vena cava	-	X
	Tricuspid valve	-	X
	Umbilical vein	-	X
	Aorta on LVOT View	-	X
	Aorta on RVOT or 3 vessels view	-	X
	Pulmonary artery trunk on 3 vessels View	-	X
	Pulmonary artery with visible bifurcation	-	X
	Portal sinus	-	X
	Bowels	X	X
	Spleen	-	X
	Gallbladder	-	X
	Bladder	X	X
	Trachea	-	-
	Liver	-	X
	Lungs	-	X
	Ribs	X	X
	Sagittal heart	X	-
CRL/NT/Profile views & structures			
CRL Profile/NT Corpus Callosum	Nasal bone	-	-
	Diencephalon	X	-

View name	Structures to be detected	First Trimester T1	Second/Third Trimesters T2/T3
	Fourth ventricle on NT view	X	-
	Nuchal translucency	-	-
	Palate	X	X
	Corpus Callosum	-	-
	Liquid space under the chin	X	-
	Midbrain tectum	-	-
	Choroid plexus on sagittal plane	-	-
	Cisterna magna on NT view	X	-
	Brainstem on NT view	X	-
	Tip of the mandible	-	-
Placenta views			
Placenta / Cervix	Cervix	-	X
	Maternal bladder	-	X
	Placenta	-	X
Spine views			
Sagittal spine	Cervical Spine	-	X
	Lumbar Spine	-	X
	Sacral Spine	-	X
Facial views			
Lips and nose Orbits Coronal face	Lenses	-	-
	Orbits	-	X
	Nose tip	-	X

View name	Structures to be detected	First Trimester T1	Second/Third Trimesters T2/T3
	Nare	-	X
	Upper lip	-	X
	Lower lip	-	X

List of localization that can be automatically identified (bounding box)

Bounding boxes can be automatically detected and displayed for the views and anatomical structures.

View name	Structure name
Brain views & structures	
Choroid plexus	Thalami/cerebral peduncles on axial view
Thorax and Heart views & structures	
-	Left Ventricle
	Left Atrium
	Ribs

Quality criteria are related to:

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

For instance the transthalamic view, at the second and third trimester, Sonio Detect can evaluate the following criteria.

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

Quality criteria	1st trimester	2nd/3rd Trimester
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	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 v3 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 v3 and the predicate differ in the clinical outcomes. Sonio Detect v3 outputs localization for views and anatomical structures whereas the predicate Sonio Detect v2 does not output localization.

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 v3 to the predicate Sonio Detect v2 cleared in K240406.

Table 5: Comparison of technological characteristics

Items	Predicate device: Sonio Detect v2	Proposed device : Sonio Detect v3
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)

Items	Predicate device: Sonio Detect v2	Proposed device : Sonio Detect v3
Features	- 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.	- Sonio Detect automatically detect views - Sonio Detect automatically detect anatomical structures within the supported views - Sonio Detect automatically verifies the quality criteria and characteristics of the supported views. - Sonio Detect automatically localizes views and anatomical structures
Algorithm Methodology	Artificial Intelligence Lecture of biometrics Colorimetry for 3D and Doppler	Artificial Intelligence
Platform	Secure cloud-based and stand-alone software compatible with ultrasound system from GE Medical, Samsung, Canon and Philips	Secure cloud-based and stand-alone software compatible with ultrasound system from GE Medical, Samsung, Canon and Philips

Sonio Detect v3 and its predicate differs in the following:

- Features : Sonio Detect v3 automatically localizes views and anatomical structures.
- Algorithm Methodology : Sonio Detect v3 uses Artificial Intelligence and does not include lectures of biometrics and colorimetry for 3D and Doppler.

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 22496 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 v3 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 PE (95%CI)	Specificity PE (95%CI)
Automatic detection of 14 T1 fetal ultrasound images	0.886 (0.876-0.898)	0.981 (0.979-0.982)
Automatic detection of 40 T2/T3 fetal ultrasound images	0.901 (0.896-0.905)	0.993 (0.993-0.994)
Automatic localization of 1 view (T1)	mIoU: 0.777 (0.743-0.811)	
Automatic detection of 1 fetal brain anatomical structure on the view “Transthalamic” at T1	0.815 (0.751-0.871)	0.938 (0.901-0.973)
Automatic detection of 7 fetal brain anatomical structures on the views “Transthalamic”, “Transventricular”, “Transcerebellar” at T2/T3	0.941 (0.934-0.947)	0.951 (0.943-0.958)
Automatic detection of 8 fetal thorax and heart anatomical structures on the views “4 chambers”, “LVOT”, “RVOT”, “Three vessels”, “Three vessels and trachea”, “Abdominal Circumference”, “Axial view of the kidneys”, “Diaphragm”, “Abdominal cord insertion” at T1	0.872 (0.848-0.892)	0.921 (0.913-0.928)
Automatic detection of 24 fetal thorax and heart anatomical structures on the views “Four chambers”, “LVOT”, “RVOT”, “Three vessels”, “Three vessels and trachea”, “Abdominal Circumference”, “Axial view of the kidneys”, “Diaphragm”, “Abdominal cord insertion” at T2/T3	0.914 (0.906-0.920)	0.963 (0.961-0.965)
Automatic detection of 3 fetal placenta anatomical structures on the view “Placenta / Cervix” at T2/T3	0.887 (0.874-0.899)	0.962 (0.950-0.972)

Items (fetal ultrasound views, anatomical structures and characteristics automatically detected)	Sensitivity PE (95%CI)	Specificity PE (95%CI)
Automatic detection of 6 fetal Sagittal Fetus anatomical structures on the views “Crown Rump Length”, “Profile” at T1	0.869 (0.849-0.896)	0.848 (0.822-0.875)
Automatic detection of 1 fetal Sagittal Fetus anatomical structures on the views “Profile” at T2/T3	0.883 (0.852-0.913)	0.800 (0.754-0.842)
Automatic detection of 5 fetal Coronal Face anatomical structures on the views “Lips and nose”, “Orbits”, “Coronal face” at T2/T3	0.922 (0.897-0.947)	0.901 (0.883-0.923)
Automatic detection of 3 fetal Spine anatomical structures on the view “Sagittal Spine” at T2/T3	0.839 (0.818-0.862)	0.852 (0.829-0.873)
Automatic localization of 1 brain anatomical structures (on T1)	mIoU: 0.683 (0.632-0.734)	
Automatic localization of 3 thorax and heart anatomical structures (on T1)	mIoU: 0.679 (0.653-0.705)	
Automatic detection of the Anterior placenta location for the view “Placenta / Cervix” at T2/T3	0.925 (0.894-0.949)	0.918 (0.885-0.948)
Automatic detection of the Posterior placenta location for the views “Placenta / Cervix” at T2/T3	0.918 (0.885-0.948)	0.925 (0.894-0.949)
Automatic detection of the “Female sex” for fetal sex for the view “External Genitalia” at T2/T3	1.000 (1.000-1.000)	0.985 (0.969-1.000)
Automatic detection of the “Male sex” for fetal sex for the view “External Genitalia” at T2/T3	0.985 (0.969-1.000)	1.000 (1.000-1.000)

Additionally, the performance for the detection of views and structures was also validated for subgroups including: Ultrasound machine manufacturer, BMI, maternal age, confounding cases, Image quality, geography, 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 intended users, intended use and clinical applications are similar to those of the predicate device Sonio Detect v2, the cleared version in K240406.

The clinical outcome differences identified and discussed in Section II do not raise different questions of safety and effectiveness of the device.

The features and algorithm methodology differences identified and discussed in Section III 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 Sonio Detect v2 (K240406).