Sonio
Florian Akpakpa
Head of Regulatory Affairs and Quality Assurance
17 rue du Faubourg Montmartre
Paris, 75009
France

February 21, 2025

Re: K243614
Trade/Device Name: Sonio Suspect
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: January 24, 2025
Received: January 24, 2025

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.

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
Imaging Software Team
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)*

K243614

Device Name

Sonio Suspect

Indications for Use *(Describe)*

Sonio Suspect is intended to assist interpreting physicians, during or after fetal ultrasound examinations, by automatically identifying and characterizing abnormal fetal ultrasound findings on detected views, using machine learning techniques.
The device is intended for use as a concurrent reading aid on acquired images, during and/or after fetal ultrasound examinations.
The device provides information on abnormal findings that may be useful in rendering potential diagnosis.
Patient management decisions should not be made solely on the results of the Sonio Suspect analysis.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

I. Submitter

Applicant:	Sonio 147 Rue d'Aboukir, 75002, Paris France
Primary Contact Person:	Florian Akpakpa Director Regulatory Affairs and Quality Assurance Sonio Phone: +33 6 19 38 71 45 Email: florian.akpakpa@sonio.ai
Date Prepared:	February 19, 2025

II. Device

Device Trade Name:	Sonio Suspect
Classification Name:	21 CFR 892.2060 - Radiological computer-assisted diagnostic software for lesions suspicious of cancer
Regulatory Class:	Class II
Product Code:	POK (primary)

III. Predicate Device

Koios DS from the manufacturer Koios Medical, Inc. cleared in K212616.

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

The following reference device was used: Sonio Detect-K240406.

IV. Device Description

Sonio Suspect is a Software as a Service (SaaS) solution that aims at helping interpreting physicians (designated as healthcare professionals i.e. HCP in the following) to identify abnormal fetal ultrasound findings during and/or after fetal ultrasound examinations.

Sonio Suspect is a web application accessible from any device connected to the internet. It can be accessed on a tablet, computer or any other support capable of providing access to a web application.

Sonio Suspect can be used by HCPs as a concurrent reading aid on acquired images, to assist them during and/or after fetal ultrasound examinations of gestational age (GA): from 11 weeks to 41 weeks. A concurrent read by the users means a read in which the device output is available during and/or after the fetal ultrasound examination.

The way Sonio Suspect is built allows the HCP to use it at any moment. The software can process any Ultrasound image file uploaded by the HCP, at any time.

Sonio Suspect can be connected through API to external devices (as an ultrasound machine) to receive images.

Sonio Suspect workflow goes through the following steps:

As soon as an image is automatically received, it is automatically detected and associated with a view (and can be manually re-associated by the HCP). Then abnormal fetal ultrasound findings linked to the view are evaluated and displayed, individually, with one of the following status:

- Suspected (abnormal findings identified on the image);
- Not Suspected (abnormal findings not identified on the image);
- Can’t be analyzed (abnormal findings not evaluated due to one or several structures not detected or if the fetal position selected is “other or unknown” while it’s required to evaluate the abnormal finding).

Each abnormal finding status can be manually overridden to Present or Not Present by the user.

The list of abnormal findings that Sonio Suspect can automatically detect is detailed in Table 1 below.

Table 1: list of Fetal Abnormal Findings in Sonio Suspect scope and their associated View, Fetal Anatomy and Gestational Age (GA)

Fetal Anatomy	Abnormal Finding	View	GA
Chest	Absence or unusual size of at least one of the 3 vessels	3 vessels	**T2/T3**
	Malposition of the great vessels	LVOT/RVOT	**T2/T3**
	Disequilibrium OR absence of at least one of the two ventricles	4 chambers	**T1/T2/T3**
	Thoracic situs inversus		
Abdominal	Abdominal situs inversus	Abdominal circumference	**T1/T2/T3**
	Non-visibility of a single stomach bubble OR abnormally big stomach		
Cephalic	Absence of the cavum septum pellucidum	Transthalamic view	**T2/T3**
	Absence of the Corpus Callosum	Corpus callosum view*	**T2/T3**

*Note: The views are automatically detected by Sonio Suspect besides the Corpus callosum view on which abnormal finding identification and characterization is done by the software when it is manually associated by the users.

V. Indications for Use

Sonio Suspect is intended to assist interpreting physicians, during or after fetal ultrasound examinations, by automatically identifying and characterizing abnormal fetal ultrasound findings on detected views, using machine learning techniques.

The device is intended for use as a concurrent reading aid on acquired images, during and/or after fetal ultrasound examinations.

The device provides information on abnormal findings that may be useful in rendering potential diagnosis.

Patient management decisions should not be made solely on the results of the Sonio Suspect analysis.

Sonio Suspect and the predicate device, Koios DS, have similar intended use in assisting interpreting physicians in analyzing ultrasound images and characterizing ultrasound image items using machine learning techniques. Both devices are used as an aid to diagnosis and provide information that may be useful in rendering potential diagnosis.

The indication for use of Sonio Suspect and the predicate device differ in the following:

- The target population: Sonio Suspect is indicated for pregnant women undergoing fetal ultrasound examinations of the fetus while Koios DS is indicated for adult female patients with soft tissue breast lesions and/or all adult patients with thyroid nodules suspicious for cancer
- Feature scope: While the predicate Koios DS, requires the user to select or confirm regions of interests (ROIs) within an image to be analyzed, Sonio Suspect automatically detects fetal ultrasound views on which abnormal fetal ultrasound findings will be identified.
- Feature scope: Koios DS allows the users to adjust, measure, and document images and output into a structured report while Sonio Suspect does not.

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

VI. Comparison of Technological Characteristics with the Predicate Device

Table 2 provides a comparison of the Technological Characteristics of Sonio Suspect to the predicate Koios DS cleared in K212616.

Table 2 - comparison of the Technological Characteristics of Sonio Suspect to the predicate

Items	Predicate: Koios DS	Proposed device: Sonio Suspect
Manufacturer name	Koios Medical	Sonio
Device name	Koios DS	Sonio Suspect
Regulation Number	21 CFR 892.2060 21 CFR 892.2050	21 CFR 892.2060
Product code	POK QIH	POK
Image modality	Breast Ultrasound Data Thyroid Ultrasound DataUltrasound images	Fetal Ultrasound images
Algorithm Methodology	Computer vision Machine Learning Techniques	Computer vision Machine Learning-Based Algorithm
Platform	ASP.NET web application deployed to a Microsoft IIS web server inside a Windows operating system environment	Secure cloud-based and stand-alone software compatible with an ultrasound system

The technical principle of both Sonio Suspect and the predicate Koios DS is the characterization of ultrasound images items using computer vision and machine learning-based algorithms. Both devices use ultrasound images modality for analysis.

Sonio Suspect differs from Koios DS in the following:

- Operating platform: Sonio Suspect is a secure cloud-based and standalone software compatible with ultrasound systems while Koios DS the predicate is a ASP.NET web application deployed to a Microsoft IIS web server inside a Windows operating system environment.

However, these differences should not raise new questions regarding the 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

Performance testing - Bench

Sonio conducted a standalone performance testing in accordance with 21 CFR §892.2060 special control 1(iv). The testing was conducted on a dataset of 8745 fetal ultrasound images from 1115 exams collected across 75 sites, 64 of which are located in the United States, representing the intended use population. This global validation dataset was independent of the data used during model development (training/fine tuning/internal validation) and the establishment of device operating points.

The results of the standalone performance testing demonstrated that Sonio Suspect automatically detects abnormal fetal ultrasound findings with a sensitivity of 93.2% (Confidence Interval of [91.6%-94.6%]) and a specificity of 90.8% (Confidence Interval of [89.5%-92.0%]).

Table 3 below summarizes Sonio Suspect's performance results.

The abnormal finding "Abdominal Situs Inversus" has the highest performance in terms of both sensitivity (99.3%) and specificity (99.3%). The lowest sensitivity (87.7%) is associated with the abnormal finding "Malposition of the great vessels" and the lowest specificity (81.5%) with the abnormal finding "Absence or unusual size of at least one of the 3 vessels".

Table 3: Performance of Sonio Suspect for abnormal finding detection.

Fetal Anatomy	Gestational Age	Abnormal Finding	Sensitivity	Specificity
			Point Estimate (95% bootstrap CI)	**Point Estimate (95% bootstrap CI)**
Average Performance	**T1/T2/T3**	**Average Performance**	**0.932 (0.916, 0.946)**	**0.908 (0.895, 0.920)**
Chest	T2/T3	Malposition of the Great Vessels	0.877 (0.840, 0.908)	0.933 (0.905, 0.957)
		Absence or unusual size of at least one of the 3 vessels	0.959 (0.926, 0.983)	0.815 (0.759, 0.872)
	T1/T2/T3	Disequilibrium OR absence of at least one of the two ventricles	0.900 (0.861, 0.934)	0.817 (0.782, 0.851)
		Thoracic Situs Inversus	0.961 (0.930, 0.987)	0.958 (0.927, 0.982)
Abdominal	T1/T2/T3	Abdominal Situs Inversus	0.993 (0.976, 1.000)	0.993 (0.984, 1.000)
		Non-visibility of a single stomach bubble OR abnormally big stomach	0.880 (0.780, 0.946)	0.964 (0.950, 0.977)
Cephalic	T2/T3	Absence of the Cavum Septum Pellucidum	0.911 (0.861, 0.956)	0.925 (0.882, 0.962)
		Absence of the Corpus Callosum	0.976 (0.952, 0.994)	0.859 (0.805, 0.907)

Additionally, the performance for the detection of abnormal fetal ultrasound findings was also validated for subgroups including Indication of examination, Race, Ethnicity, BMI, Gestational Age (GA), Maternal age, Manufacturer, Geography (OUS and US), Finding Status (Finding-positive and Finding-negative images) and Fetal Anatomy, and detailed subgroup analysis results are reported in the User Manual.

Sonio Suspect was validated only on GE, Philips, Samsung and Canon Ultrasound devices.

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

Performance testing - Clinical

Sonio conducted a clinical performance testing in accordance with 21 CFR §892.2060 special control 1(ii) and 1(iii). A pre-market fully-crossed multiple reader, multiple case (MRMC) retrospective reader study was conducted to determine the impact of Sonio Suspect on reader accuracy in identifying abnormal fetal ultrasound findings. The MRMC study consisted of two independent reading sessions separated by a washout period of at least 28 days in order to avoid memory bias.

The primary objective of this study was to determine whether the performance of readers assisted by Sonio Suspect ("Assisted") was superior to the performance of readers when not assisted by Sonio Suspect ("Unassisted").

13 readers (5 MFM, 6 OB/GYN and 2 Diagnostic radiologists of 1-30+ years' experience) each evaluated 750 fetal ultrasound images (between 11 and 41 weeks) under both "Assisted" and "Unassisted" reading settings. The dataset included 287 distinct exams from 47 sites, including 37 sites which are located in the United States. For each image, each reader was required to provide a binary determination of the presence or absence of an abnormal finding and to provide a score representing their confidence in their annotation.

The results of the study demonstrated that the accuracy of readers in identifying abnormal findings was superior when "Assisted" by Sonio Suspect than when "Unassisted". Particularly, the AUC in the "Unassisted" reading setting is estimated at 68.9%, whilst the AUC in the "Assisted" reading setting is estimated at 90.0% which represents a significant difference of 21.9%, as shown in Figure 1 and Table 4 below.

Figure 1: ROC curves averaged over all readers and over all abnormal findings for "Assisted" (red) and "Unassisted" (blue) reading settings.

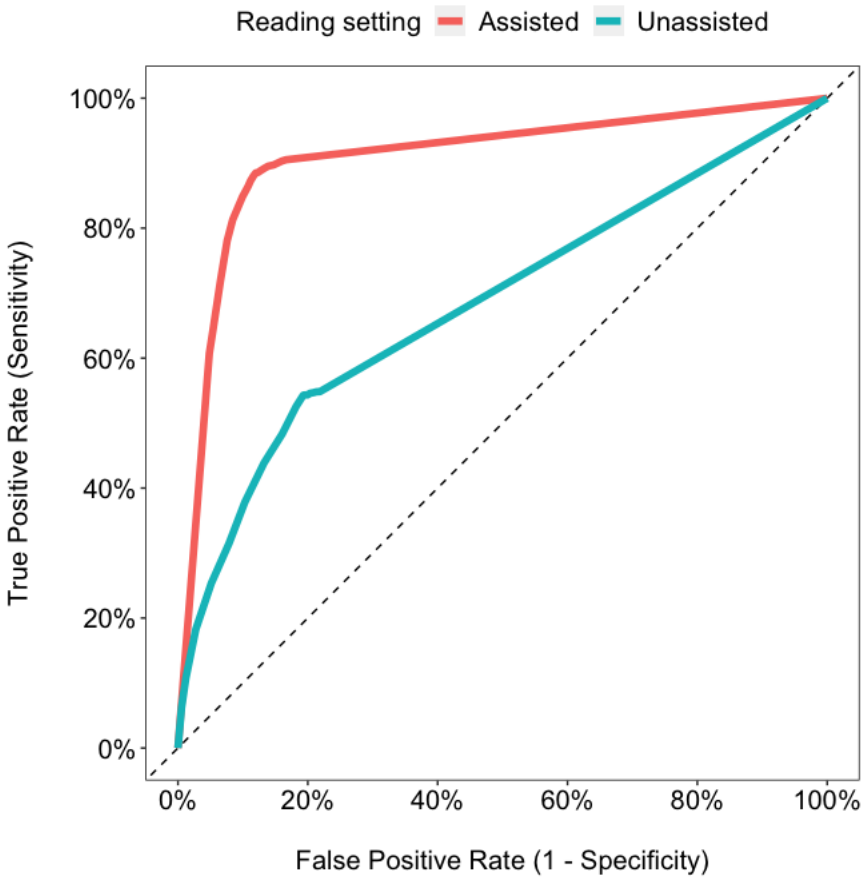


Table 4: AUCDelta, AUCUnassisted, AUCAssisted over all Readers per Abnormal Finding. (CI = Confidence Interval)

Per Abnormal Finding	N of finding-positive images	N of finding-negative images	AUC_{Delta}	$AUC_{Unassisted}$	$AUC_{Assisted}$
			Point Estimate (95% BDG CI)	Point Estimate (95% BDG CI)	Point Estimate (95% BDG CI)
Overall	**250**	**500**	**0.219 (0.185, 0.253)**	**0.689 (0.65, 0.73)**	**0.909 (0.886, 0.931)**
Abdominal Situs Inversus	32	143	0.258 (0.177, 0.339)	0.696 (0.602, 0.789)	0.953 (0.913, 0.994)
Absence of at least one of the 2 ventricles OR disequilibrium of the 2 ventricles	31	145	0.174 (0.1, 0.248)	0.742 (0.668, 0.816)	0.916 (0.877, 0.954)
Absence of the cavum septum pellucidum	31	55	0.317 (0.249, 0.384)	0.567 (0.52, 0.614)	0.884 (0.81, 0.957)
Absence of the corpus callosum	31	55	0.253 (0.206, 0.3)	0.646 (0.599, 0.694)	0.899 (0.851, 0.948)
Absence of the stomach OR presence of two stomachs	31	144	0.114 (0.071, 0.158)	0.84 (0.785, 0.895)	0.955 (0.916, 0.993)
Absence or unusual size of at least one of the 3 vessels	31	55	0.168 (0.097, 0.239)	0.736 (0.674, 0.798)	0.904 (0.852, 0.956)
Great vessels malposition	31	110	0.256 (0.183, 0.329)	0.616 (0.555, 0.676)	0.872 (0.809, 0.934)
Thoracic situs inversus	32	144	0.29 (0.231, 0.349)	0.616 (0.559, 0.672)	0.906 (0.855, 0.957)

Figure 2 and 3 below show that the "Assisted" reading curve consistently lies above the "Unassisted" curve across all 8 abnormal findings and all 13 readers, indicating the improved performance of reader accuracy in identifying abnormal findings with Sonio Suspect. This consistent pattern highlights Sonio Suspect's effectiveness in improving reader accuracy across a variety of abnormal findings and regardless of individual variability.

Figure 2: "Assisted" (red) and "Unassisted" (blue) ROC curves for each abnormal finding

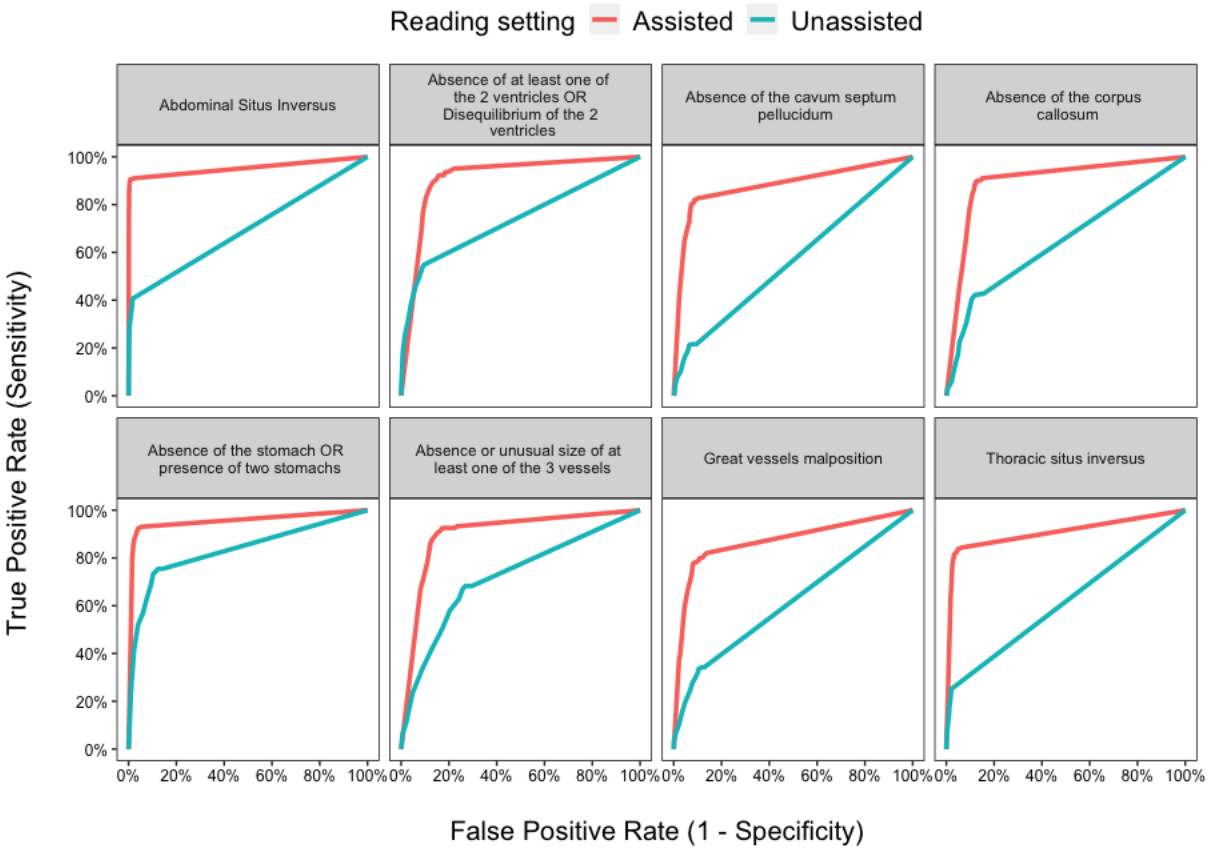
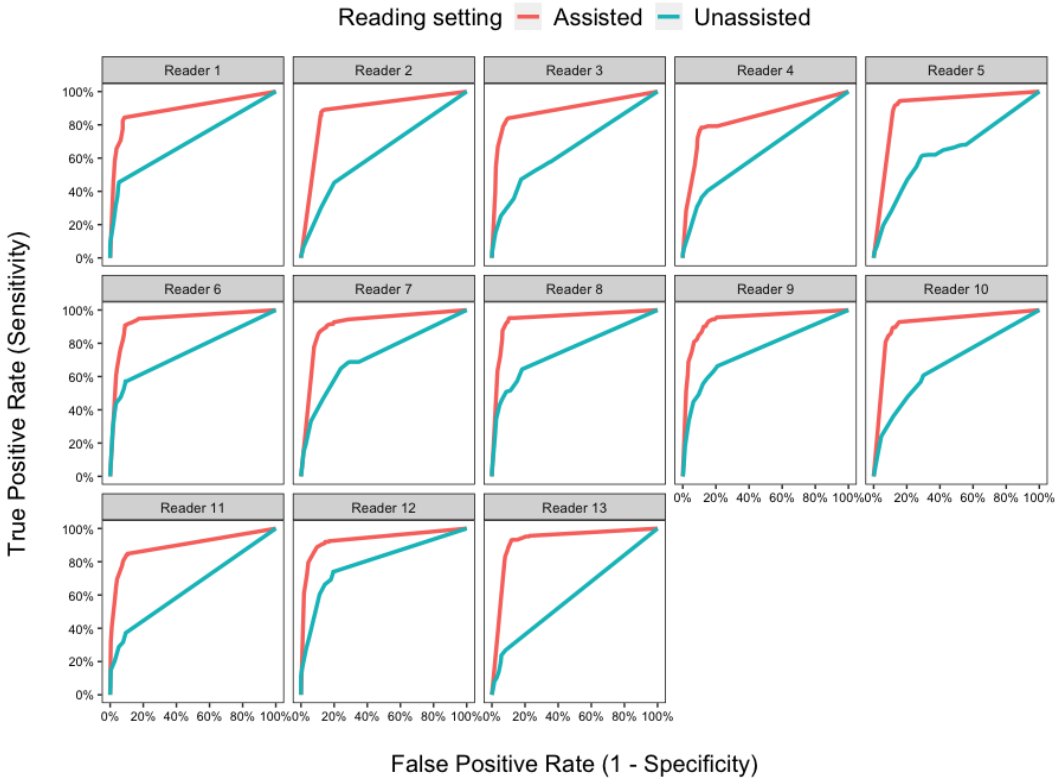


Figure 3: "Assisted" (red) and "Unassisted" (blue) ROC curves for each reader



VIII. Conclusions

The conclusions drawn from the standalone and clinical studies demonstrate that Sonio Suspect is substantially equivalent to the predicate device Koios DS cleared in K212616.
The special controls for 21 CFR 892.2060 regulation are satisfied by demonstrating the effectiveness of the device in both the standalone testing and the clinical testing, showing the superiority of "Assisted" versus "Unassisted" readings in the clinical testing and communicating testing results in the labeling.
Sonio Suspect intended use, clinical outcome, and clinical applications are similar to those of the predicate device. The technological characteristics differences identified and discussed in Section VI do not raise any different questions of safety and effectiveness of the device.
Thus, Sonio Suspect is substantially equivalent to its predicate Koios DS cleared in K212616.