June 4, 2026

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

Re: K261519
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, QIH
Dated: May 7, 2026
Received: May 7, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Jessica Lamb, PhD
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

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.	K261519

Please provide the device trade name(s).

Sonio Suspect

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K261519

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 Compliance Officer Sonio Phone: +33 6 19 38 71 45 Email: florian.akpakpa@sonio.ai
Date Prepared:	May 7th, 2026

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

The predicate device for this Special 510(k) is Sonio Suspect, cleared under K243614.

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

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 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.

Sonio Suspect was previously cleared under K243614 as a cloud-based web application (Web-Based Application configuration). This Special 510(k) submission addresses the addition of a new deployment configuration: the Integration into Third-Party Ultrasound Systems configuration (the "Integration Configuration").

Sonio Suspect is now available in two software configurations:

- **Web-Based Application**: Sonio Suspect may be accessed as a cloud-based web application via secure internet connection using a compatible device (e.g., computer or tablet). In this configuration the data processing is performed remotely in the cloud.
- **Integration configuration**: Sonio Suspect may be integrated into third-party medical devices, such as ultrasound systems, through defined software interfaces. In this configuration:
    - Sonio will supply the C++ algorithm package to the third-party manufacturer and provide integration support as needed
    - The third-party manufacturer is responsible for implementation of the user interface, system integration, and validation of the final device.

The device change consists of the migration of the Sonio Suspect algorithms from Python (cleared version) to C++ programming language to enable integration into third-party ultrasound systems. The following elements remain unchanged from K243614:

- Algorithmic logic, model weights, and decision thresholds
- Intended use and indications for use
- Intended users (MFMs, OB/GYNs, radiologists)
- Clinical functionality and performance specifications

The differences between configurations are limited to the implementation language (Python vs. C++), runtime environment (cloud-based vs. embedded in third-party systems), deployment model, and user interface responsibility.

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.

Comparison to the Predicate Device

The indications for use of the Sonio Suspect Integrated into Third-Party Systems configuration are identical to those of the cleared web-based application (K243614). No new indications for use, contraindication, warnings, or precautions are introduced by this configuration.

VI. Comparison of Technological Characteristics with the Predicate Device

The predicate for this Special 510(k) is the Sonio Suspect Web-Based Application, cleared under K243614. Table 1 below summarizes the comparison of technological characteristics.

Table 1- comparison of the Technological Characteristics

Items	Predicate: Sonio Suspect Web-Based Application (K243614)	Proposed device: Sonio Suspect Integration Configuration
Manufacturer name	Sonio	Sonio
Device name	Sonio Suspect	Sonio Suspect
Regulation Number	21 CFR 892.2060 21 CFR 892.2050	21 CFR 892.2060 21 CFR 892.2050
Product code	POK QIH	POK QIH
Image modality	Fetal Ultrasound images	Fetal Ultrasound images
Algorithm Methodology	Computer vision Machine Learning-Based Algorithm	Computer vision Machine Learning-Based Algorithm-Identical to predicate

Items	Predicate: Sonio Suspect Web-Based Application (K243614)	Proposed device: Sonio Suspect Integration Configuration
Platform/Deployment	SaaS / cloud-based web application; data processing performed remotely in the cloud; accessed via secure internet connection through a web browser	The Sonio Suspect core algorithm is integrated into a third-party ultrasound system through defined software interfaces. The third-party manufacturer is responsible for the user interface, system integration, and validation of the final integrated device.
Programming Language	Python	C++ rewritten from the cleared Python based algorithm without changes to the algorithmic logic, model weights, decision thresholds, and clinical functionality. Bench testing confirmed that the Integration configuration performs consistently with the cleared performance.
Core Algorithm	Machine Learning-Based Algorithm	Identical to predicate; underlying algorithm, intended use, and performance characteristics remain unchanged
Data Processing Location	Cloud-based (Sonio-managed)	Locally within the third-party ultrasound system
Performance	Sensitivity: 93.2% (95% CI: 91.6%–94.6%) Specificity: 90.8% (95% CI: 89.5%–92.0%)	Sensitivity: 92.5% (95% CI: 90.9%–93.9%) Specificity: 90.4% (95% CI: 89.1%–91.7%)

These differences do not raise new questions regarding the safety and effectiveness of the device when used as labeled. The underlying algorithmic logic, intended use, target population, image modality, and clinical outcomes are identical across both configurations.

Sonio Suspect (Integration Configuration) is substantially equivalent to the predicate device, Sonio Suspect (Web-Based Application), cleared under K243614.

The intended use, indications for use, target population, intended users, image modality, and clinical outcomes are identical between the Integration Configuration and the predicate. The differences between the two configurations are limited to the implementation language, runtime environment, deployment model, and user interface responsibility. These differences do not raise new questions of safety and effectiveness.

Performance bench testing was conducted using the same protocol, dataset, statistical analysis plan, and acceptance criteria applied in K243614. All predetermined acceptance criteria were

met, confirming that the Integration Configuration performs consistently with the cleared Web-Based Application configuration (K243614).

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 was conducted for the Integration Configuration in accordance with ISO 13485 Cl. 7.3 and FDA's Special 510(k) Program guidance (September 2019), and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, Content of Premarket Submissions for Device Software Functions. Software verification and validation testing were conducted, and the following documentation was provided:

- Risk Analysis
- Design Reviews
- Software Development Lifecycle
- Algorithm Verification (Algorithm internal validation)
- Software units verification
- Software system testing (with a representative third-party ultrasound system)
- Cybersecurity testing

Performance testing - Bench

As a design control measure, performance bench testing was conducted to assess the potential impact of the Integration Configuration on device performance against the endpoints and acceptance criteria established under K243614.

Results: All predetermined acceptance criteria for the primary endpoint were met for all abnormal findings in scope. No unexpected issues were identified during bench testing. The performance test results confirmed that the Integration Configuration performs consistently with the cleared performance thresholds. A direct comparison of bench test outputs provided in Table 2 below demonstrated consistent performance between the two configurations, confirming that the migration from Python to C++ and the associated changes to the runtime environment and deployment model did not adversely affect device performance. No deviations from the cleared bench test protocol were made. Table 2 below summarizes the bench testing results for the primary endpoint, presented alongside the K243614 reference result

Table 2: Performance of Sonio Suspect for abnormal finding detection (K243614 Reference vs. Integration Configuration),
PE= Point Estimate, CI = Confidence Interval

Fetal Anatomy	Gestational Age	Abnormal Finding	Web Application (K243614)		Integration Configuration	
			Sensitivity	Specificity	Sensitivity	Specificity
			Point Estimate (95% bootstrap CI)	Point Estimate (95% bootstrap CI)	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)**	**0.925 (0.909-0.939)**	**0.904 (0.891-0.917)**
Chest	T2/T3	Malposition of the Great Vessels	0.877 (0.840, 0.908)	0.933 (0.905, 0.957)	0.876 (0.837-0.912)	0.934 (0.906-0.957)
		Absence or unusual size of at least one of the 3 vessels	0.959 (0.926, 0.983)	0.815 (0.759, 0.872)	0.952 (0.918, 0.978)	0.819 (0.765, 0.874)
	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)	0.882 (0.836, 0.920)	0.815 (0.781, 0.850)
		Thoracic Situs Inversus	0.961 (0.930, 0.987)	0.958 (0.927, 0.982)	0.949 (0.914, 0.983)	0.947 (0.918, 0.972)
Abdominal	T1/T2/T3	Abdominal Situs Inversus	0.993 (0.976, 1.000)	0.993 (0.984, 1.000)	0.975 (0.952, 0.993)	0.974 (0.959, 0.988)
		Non-visibility of a single stomach bubble OR abnormally big stomach	0.880 (0.780, 0.946)	0.964 (0.950, 0.977)	0.880 (0.785, 0.946)	0.965 (0.950, 0.978)
Cephalic	T2/T3	Absence of the Cavum Septum Pellucidum	0.911 (0.861, 0.956)	0.925 (0.882, 0.962)	0.913 (0.863, 0.956)	0.925 (0.882, 0.964)
		Absence of the Corpus Callosum	0.976 (0.952, 0.994)	0.859 (0.805, 0.907)	0.976 (0.952, 0.993)	0.858 (0.804, 0.908)

Additionally, for both Web-based Application and Integration Configuration, 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.

Sonio Suspect Integration Configuration has been validated against minimum hardware requirement specifications and can be integrated with any third-party ultrasound system that meets these requirements.

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

VIII. Conclusions

Sonio Sonio Suspect (Integration Configuration) is substantially equivalent to the predicate device, Sonio Suspect (Web-Based Application), cleared under K243614. The intended use, indications for use, target population, intended users, image modality, clinical outcomes, and underlying algorithmic logic are identical across both configurations.

The device change is limited to the rewriting of the algorithms from Python to C++ and the associated changes to the runtime environment and deployment model. Performance bench testing, conducted using the same protocol, dataset, statistical analysis plan, and acceptance criteria as K243614, confirmed that the Integration Configuration performs consistently with the cleared performance thresholds. All predetermined acceptance criteria were met.

The technological differences identified do not raise new questions regarding the safety and effectiveness of the device when used as labeled. Thus, Sonio Suspect (Integration Configuration) is substantially equivalent to the predicate device Sonio Suspect (Web-Based Application), cleared under K243614.