December 22, 2025

BioticsAI, Inc.
% Mary Vater
Director of Regulatory Affairs
Innolitics LLC
1101 West 34th St. #550
Austin, Texas 78705

Re: K250959
Trade/Device Name: BioticsAI
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, QIH
Dated: November 26, 2025
Received: November 26, 2025

Dear Mary Vater:

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,

Lora D. Weidner, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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.	K250959

Please provide the device trade name(s).

BioticsAI

Please provide your Indications for Use below.

BioticsAI is intended to analyze fetal ultrasound images and frames (DICOM instances) using machine learning techniques to automatically detect views, detect anatomical structures within the views and to facilitate quality criteria verification and characteristics of the views.

The device is intended for use by Healthcare Professionals as a concurrent reading aid during and after 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)

K250959

1. CONTACT INFORMATION

Company Name	BioticsAI, Inc.
Address	455 Market St STE 1940, United States
Phone Number	+1.925.320.1532
Company Representative	Mr. Salman Khan
Email	salman@biotics.ai
Primary Contact	Mrs. Mary Vater
Primary Contact Phone Number	+1.913.523.6988
Primary Contact Email	fda@innolitics.com
Date Summary Prepared	Dec. 2, 2025

2. DEVICE INFORMATION

Trade Name	BioticsAI
Common Name	Ultrasonic pulsed doppler imaging system
Classification Name	System, Imaging, Pulsed Doppler, Ultrasonic
Regulation Number	21 CFR 892.1550
Product Code(s)	IYN, IYO, QIH

3. PREDICATE DEVICE

Predicate Device Name	Sonio Detect
Manufacturer	Sonio
510(k) Number	K240406
Product Code	IYN, IYO, QIH
Regulation Number	21 CFR 892.1550

4. DEVICE DESCRIPTION

4.1. Description

BioticsAI is a software used by OB/GYN care centers for prenatal ultrasound review and reporting. BioticsAI uses artificial intelligence (A.I.) to automatically annotate ultrasound images with fetal anatomical planes and structures to facilitate ultrasound review and report generation for fetal ultrasound anatomical scans. It serves as concurrent reading aid for ultrasound images both during and after a fetal anatomical ultrasound examination.

BioticsAI is a Software as a Service (SaaS) solution that aims at helping sonographers, OB/GYNs, MFMs and Fetal surgeons (all three designated as healthcare professionals i.e. HCP) to perform their routine fetal ultrasound examinations in real-time.

BioticsAI can be used by Healthcare Professionals HCPs during fetal ultrasound exams for Trimester 2 of the fetus, during which a fetal anatomy exam is typically captured (typically conducted between 18-22 weeks but can be captured on gestational ages ranging from 18 up to 39 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

BioticsAI requires the following SaaS accessibility from internet browser.

BioticsAI receives DICOM instances, which consist of still fetal ultrasound images (in the form still image captures or individual frames from a multi-frame instance) from the ultrasound machine, which are submitted by the performing healthcare professional from the clinic's network, either during the screening or post-screening and performs the following:

- Automatically detect fetal anatomical planes (2D ultrasound views).
- Automatically flag high-level anatomical features (e.g., "head", "thorax", "limb detected in image", etc).
- Automatically detect specific anatomical structures within supported planes/views (i.e. "cerebellum, csp, and cisterna magna found in transcerebellar plane image").
- Facilitate quality verification of supported planes by determining whether the expected anatomical structures, as informed by the latest ISUOG and AIUM guidelines, are present in the ultrasound image. The quality assessment focuses on the presence or absence of these anatomical structures.

BioticsAI automatically identifies fetal anatomical views and anatomical structures captured during the screening. It uses green highlights to indicate successfully detected planes and structures. Red highlights are used to flag instances where the model could not detect an expected anatomical view or structure, even though it is a supported feature. Yellow highlights indicate views or structures that require manual verification (when the AI cannot determine whether anatomical features are present or absent because it is not yet supported by our product).

The end user can interact with the software to override BioticsAI's outputs. Specifically, users can unassign or assign an image to a plane or high level anatomical feature, and update the status of quality criteria for structures by changing it from "found" to "not found" or vice versa. Users have the flexibility to review and edit these assignments at any point during or after the exam.

The end user then has the ability to include the information gathered during quality and image review automatically in a final report via a button called "Confirm Screening Results", automatically filling out a

report template with identified planes and structures. The report can then be further exported to the clinic's PACS over DIMSE via a populated DICOM SR.

BioticsAI also provides a standard DICOM Viewer for viewing DICOM instances, and obstetrics ultrasound report templates for manually creating ultrasound reports without the AI based functionality as described above.

To further explain the AI-driven outputs provided by the device, we describe the three primary AI components below:

- **AI-1: High-Level Anatomy Classification**

  Provides a multi-label classification of the general anatomical region depicted in the image (e.g., head/brain, face, thorax/chest, abdomen, limbs). These categories correspond to standard high-level anatomy groupings used in fetal ultrasound interpretation.

- **AI-2: Per-Class Top-1 Fetal Plane Classification**

  Provides fetal anatomical plane classifications using a *per-class Top-1* approach. A fetal "plane" refers to a standardized cross-sectional view defined by ISUOG and aligned with AIUM guidance for mid-trimester fetal anatomy scans. For each anatomical plane category, the model outputs the image with the single highest-confidence prediction (Top-1) associated with that class.

- **AI-3: Fetal Anatomical Structure Classification**

  Provides multi-label identification of fetal anatomical structures (e.g., cerebellum, cisterna magna, cerebral peduncles), generated from the model's segmentation head and refined through post-processing filters that enforce plane-structure consistency and remove non-intended labels.

The list of views, fetal planes, and anatomical structures automatically detected by AI-1, AI-2, and AI-3's outputs and verified by the software are detailed in tables 1, 1.1, 2, and 3 below:

Table 1: AI-1 Outputs / High Level Anatomy Classification Label Criteria

Label	Label Criteria
Head (also referred to as "Brain")	One of "Transcerebellar" plane, "Transthalamic" plane, or the "Transventricular" plane
Face	One of "Median Facial Profile" plane, "Coronal Plane of Upper Lip, Nose, and Nostrils" plane, or "Orbits, Lenses" plane
Thorax/Chest (Also referred to as "Heart Screening Planes")	One of the "Right Ventricular Outflow Tract" plane, "Three-Vessel View" plane, "Three-Vessel and Trachea View" plane, "Left Ventricular Outflow Tract" plane, or "Thorax Four-Chamber Heart View" plane
Abdomen	One of "Bladder Plane ", "Kidneys Plane", "Stomach Umbilical Plane", or "Cord Insertion Plane"
Limbs	Do one or more of these elements exist: ● The tibia is present ● The fibula is present

	● The foot is present ● The ankle region (relationship between the tibia, fibula, and foot) is present ● The humerus is present ● The radius is present ● The ulna is present ● The wrist region (the relationship between the hand and the 2 forearm bones is present) ● The hand is present ● The femur is present

Table 1.1 "Heart Screening Planes" Inclusion Categories

Inclusion Categories
Heart: Thorax 4 Chamber Heart Plane
Heart: 3VT Heart Plane
Heart: 3VV Heart Plane
Heart: RVOT Plane
Heart: LVOT Plane

Table 2: AI-2 Outputs / Per Class Top-1 Plane Classification Labels

Labels
Abdomen: Bladder Plane
Abdomen: Cord Insertion Plane
Abdomen: Kidneys Plane
Abdomen: Stomach Umbilical Vein Plane
Face: Coronal Plane of Upper Lip, Nose, and Nostrils
Face: Median Facial Profile Plane
Face: Orbits, Lenses Plane
Head: Transcerebellar Plane
Head: Transthalamic Plane
Head: Transventricular Plane
Heart: 4 Chamber Heart Plane
Limbs: Femur Plane

Spine: Sagittal Spine Plane

Table 3: AI-3 Outputs / Fetal Anatomical Structures and Regions Label Criteria

Structure	Views the Structure is found in (hence we only predict the visibility of structures within these views)
Bladder	Abdomen Bladder
Cord Insertion	Abdomen Cord Insertion
Kidney	Abdomen Kidneys
Abdominal Aorta	Abdomen Stomach Umbilical
Inferior Vena Cava	Abdomen Stomach Umbilical
Stomach Shadow	Abdomen Stomach Umbilical
Floating Ribs	Abdomen Stomach Umbilical Vein
Umbilical Vein	Abdomen Stomach Umbilical vein
Ossification Center Of The Spine	Abdomen Stomach Umbilical, Abdomen Kidneys, Heart Screening Planes, Thorax 4 Chamber Heart, Spine Sagittal
Lower Lip	Face Coronal Upper lip Nose Nostrils, Face Median Facial Profile
Upper Lip	Face Coronal Upper lip Nose Nostrils, Face Median Facial Profile
Chin	Face Median Facial Profile
Frontal Bone	Face Median Facial Profile
Maxilla	Face Median Facial Profile
Nasal Bone	Face Median Facial Profile
Skin Overlying The Forehead	Face Median Facial Profile
Nose	Face Median Facial Profile, Face Coronal Upperlip Nose Nostrils
Orbits	Face Orbits Lenses
Cerebellum	Head Transcerebellar
Cerebral Peduncles	Head Transcerebellar
Cisterna Magna	Head Transcerebellar
Falx Cerebri	Head Transthalamic, Head Transventricular
Septum Pellucidum	Head Transthalamic, Head Transventricular
Atria	Head Transventricular
Choroid Plexus	Head Transventricular

Lateral Ventricle Posterior Horn Walls	Head Transventricular
Parito Occipital Sulcus	Head Transventricular
CSP	Head Transventricular, Head Transthalamic
Lateral Sulcus	Head Transventricular, Head Transthalamic
Thalami	Head Transventricular, Head Transthalamic
Aorta	Heart Screening Planes
LVOT	Heart Screening Planes
Pulmonary Artery	Heart Screening Planes
RVOT	Heart Screening Planes
Superior Vena Cava	Heart Screening Planes
Thymus Gland	Heart Screening Planes
Left Ventricle	Heart Screening Planes, Thorax 4 Chamber Heart
Lungs	Heart Screening Planes, Thorax 4 Chamber Heart
Right Atrium	Heart Screening Planes, Thorax 4 Chamber Heart
Right Ventricle	Heart Screening Planes, Thorax 4 Chamber Heart
Septum Primum	Heart Screening Planes, Thorax 4 Chamber Heart
Ventricular Septum	Heart Screening Planes, Thorax 4 Chamber Heart
Descending Aorta	Heart Screening Planes, Thorax 4 Chamber Heart
Left Atrium	Heart Screening Planes, Thorax 4 Chamber Heart
Ribs	Heart Screening Planes, Thorax 4 Chamber Heart
Femur	Limbs Femur
Skin Overlying The Spine	Spine Sagittal

5. SUBJECT DEVICE INDICATIONS FOR USE

BioticsAI is intended to analyze fetal ultrasound images and frames (DICOM instances) using machine learning techniques to automatically detect views, detect anatomical structures within the views and to facilitate quality criteria verification and characteristics of the views.

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

6. SUBSTANTIAL EQUIVALENCE COMPARISON

6.1. Indications for Use Equivalence Discussion

The indications for use of the devices are nearly identical. Both devices are 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 devices are both intended for use as a concurrent reading aid during the acquisition and interpretation of fetal ultrasound images.

6.2. Device Comparison

Table 4 provides a comparison of the Technological Characteristics of BioticsAI to the predicate Sonio Detect cleared in K240406.

Table 4: Comparison of Technological Characteristics

Feature/Function	Proposed Device: BioticsAI	Predicate Device: Sonio Detect (K240406)
Manufacture Name	BioticsAI, Inc.	Sonio
Device Name	BioticsAI	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)
Intended Users	Qualified and trained healthcare professional personnel in a professional prenatal ultrasound (US) imaging environment (this includes sonographers, MFMs, OB/GYN, and Fetal surgeons)	Qualified and trained healthcare professional personnel in a professional prenatal ultrasound (US) imaging environment (this includes sonographers, MFMs, OB/GYN, and Fetal surgeons)
Features	- BioticsAI automatically detects views - BioticsAI automatically detects anatomical structures within the supported views - BioticsAI provides an interface to the operator that shows BioticsAI's automatic anatomical findings, allowing the operator to verify the quality criteria and characteristics of the supported views.	- 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 (Computer Vision)	Artificial Intelligence (Computer Vision)

Platform	Secure cloud-based software compatible with standard DIMSE integration with ultrasound systems from GE Medical	Secure cloud-based and stand-alone software compatible with ultrasound systems from GE Medical, Samsung, Canon and Philips
Real Time?	No	No
System Compatibility	BioticsAI requires the following: - Clinical support for exporting DICOM over DIMSE to BioticsAI's DICOM Adapter. - SaaS accessibility from an internet browser (recommended browser: Google Chrome).	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).

BioticsAI and its predicate differs in the following:

- the platform: BioticsAI and its predicate differ in their compatibility with ultrasound machine manufacturers, however, both devices support ultrasound systems from GE Medical.
- BioticsAI can integrate with a standard DIMSE connection that the client provides for integration within the same network as the ultrasound machine. The predicate ships a separate standard alone edge software to install on a server on the same network as an ultrasound machine for connectivity.

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

7. DISCUSSION OF PERFORMANCE TESTING

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 Verification (including unit, integration, interoperability, UI/UX testing, load testing)
- Simulated use testing (Validation)
- Performance testing
- Cybersecurity testing

Bench Testing

BioticsAI conducted a standalone performance testing on a dataset of 11,186 fetal ultrasound images in the United States across 296 patients across varying ethnicities, patient BMIs, patient ages, and gestational ages, twin pregnancies, and presence of abnormalities representative of the intended use population from a single site (across multiple ultrasound screening units and machine instances) in the United States. This dataset was independent of the data used during model development (training/fine tuning/internal validation) and establishment of device operating points.

The results of the standalone performance testing demonstrate that BioticsAI:

Table 5: Results of Standalone Performance Testing for AI-1: High-Level Anatomy Classification

Items (fetal ultrasound views detected)	Sensitivity		Specificity	
	Point Estimate	**Bootstrapping CI (95%)**	**Point Estimate**	**Bootstrapping CI (95%)**
AI-1 High Level Anatomy: Fetal "**Abdomen**" View Detection across any of: ("Bladder Plane ",, "Kidneys Plane", "Stomach Umbilical Plane", "Cord Insertion Plane")	0.953	(0.942, 0.962)	0.986	(0.984, 0.989)
AI-1 High Level Anatomy: Fetal "**Face**" View, Detection across any of: ("Median Facial Profile Plane", "Coronal Plane of Upper Lip, Nose, and Nostrils Plane", "Orbits, Lenses Plane")	0.944	(0.932, 0.956)	0.993	(0.991, 0.994)
AI-1 High Level Anatomy: Fetal "**Head**" Planes, Detection across any of: ("Transthalamic Plane", "Transventricular Plane", "Transcerebellar Plane")	0.955	(0.946, 0.964)	0.996	(0.995, 0.997)
AI-1 High Level Anatomy: Automatic detection of the Fetal "**Limbs**" characterized across, 10 potential visual elements Detection across any of: -tibia -fibula -foot -ankle region, "relationship between the tibia, fibula, and foot" -humerus -radius -ulna -wrist region, "relationship between the hand, radius, and ulna" -hand -femur	0.919	(0.895, 0.943)	0.983	(0.981, 0.985)

AI-1 High Level Anatomy: Automatic detection "**Heart** Screening" Planes, defined by any of the 5 Fetal Heart Planes ("Right Ventricular Outflow Tract Plane", "Three-Vessel View", "Three-Vessel and Trachea View", "Left Ventricular Outflow Tract Plane", "Four-Chamber Heart Plane")	0.912	(0.895, 0.928)	0.990	(0.988, 0.992)

Table 6: Results of Standalone Performance Testing for AI-2: Per-Class Top-1 Fetal Plane Classification

Class	Sensitivity Bootstrapping CI (95%)	Specificity Bootstrapping CI (95%)
abdomen_bladder	0.960 (0.940, 0.977)	0.998 (0.997, 0.998)
abdomen_cord_insertion	0.965 (0.947, 0.983)	0.998 (0.997, 0.999)
abdomen_kidneys	0.953 (0.927, 0.973)	0.998 (0.997, 0.999)
abdomen_stomach_umbilical_vein	0.990 (0.982, 0.997)	1.000 (1.000, 1.000)
face_coronal_of_upperlip_nose_nostrils	0.981 (0.968, 0.993)	0.999 (0.999, 1.000)
face_median_facial_profile	1.000 (1.000, 1.000)	0.999 (0.998, 1.000)
face_orbits_lenses	0.897 (0.863, 0.927)	0.999 (0.999, 1.000)
head_transcerebellar	0.998 (0.994, 1.000)	1.000 (0.999, 1.000)
head_transthalamic	0.923 (0.899, 0.945)	0.992 (0.991, 0.994)
head_transventricular	0.975 (0.964, 0.984)	1.000 (1.000, 1.000)
limbs_femur	0.955 (0.944, 0.966)	0.992 (0.990, 0.994)
spine_sagittal	0.909 (0.891, 0.927)	0.995 (0.993, 0.996)
thorax_lungs_four_heart_chambers	0.969 (0.954, 0.983)	0.997 (0.996, 0.998)

Table 7: Summary of Results for "AI-1: High-Level Anatomy Classification", "AI-2: Per-Class Top-1 Fetal Plane Classification", and "AI-3: Fetal Anatomical Structure Classification"

Items (fetal ultrasound views, anatomical structures and characteristics automatically detected)	Sensitivity Across Diagnostically Acceptable Images		Sensitivity Across all Image Qualities		Specificity Across all Image Qualities	
	Point Estimate	Bootstrapping CI (95%)	Point Estimate	Bootstrapping CI (95%)	Point Estimate	Bootstrapping CI (95%)
Automatic detection of 5 High-Level Fetal Anatomy Sections (Abdomen, Face, Head, Limbs, Thorax)	-	-	0.934	(0.929, 0.94)	0.989	(0.988, 0.99)
Automatic detection of 13 fetal ultrasound planes (Per-class Top-1 classification)	-	-	0.960	(0.955, 0.964)	0.997	(0.997, 0.998)
Automatic detection of 12 fetal head anatomical structures on the views "Transthalamic", "Transventricular", "Transcerebellar"	0.948	(0.935, 0.959)	0.881	(0.871, 0.891)	0.991	(0.99, 0.992)
Automatic detection of 9 fetal abdomen anatomical structures on the views "Bladder", "Kidneys", "Stomach Umbilical Vein", "Cord Insertion"	0.953	(0.941, 0.964)	0.919	(0.909, 0.93)	0.983	(0.982, 0.984)
Automatic detection of 9 fetal face anatomical structures on the views "Coronal Plane of Upper Lip, Nose, and Nostriles", "Median Facial Profile", "Orbits, Lenses"	0.983	(0.976, 0.989)	0.958	(0.951, 0.965)	0.991	(0.99, 0.992)
Automatic detection of 2 fetal spine	0.992	(0.989, 0.996)	0.975	(0.97, 0.98)	0.927	(0.921, 0.931)

anatomical structures on the views "Sagittal Spine"						
Automatic detection of 16 fetal thorax and heart anatomical structures on the views "Four Chamber", "LVOT", "RVOT", "3VV", "3VT"	0.978	(0.969, 0.985)	0.925	(0.911, 0.939)	0.989	(0.988, 0.99)

Additionally, the performance for the detection of high level anatomy, planes/views, and structures was also validated for subgroups including: BMI, maternal age, gestational age, race/ethnicity, twin vs singleton pregnancies, and presence of abnormalities when appropriate.

BioticsAI was validated only with GE Ultrasound devices and is intended only to be used with these Ultrasound vendors. The device was validated on patients aged 18 to 44 years and is not intended for use on patients younger than 18 or older than 44. The device was validated on fetal ultrasound images from 18 to 39 weeks' gestation and is not intended for use on gestational ages below 18 weeks.

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

8. CONCLUSION

BioticsAI's intended users, clinical outcome and clinical applications are similar to those of the predicate device (K240406).
The technological characteristics differences identified and discussed in Section "Comparison of Technological Characteristics with the Predicate Device" 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, BioticsAI is substantially equivalent to its predicate.