May 23, 2025

DeepEcho
Youssef Bouyakhf
Chief Executive Officer
555 East Loockerman Street
DOVER, DE 19901

Re: K242594
Trade/Device Name: DEEPECHO
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, QIH
Dated: April 23, 2025
Received: April 23, 2025

Dear Youssef Bouyakhf:

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,

JULIE SULLIVAN -S

Julie Sullivan, Ph.D.
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

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.

510(k) Number *(if known)*
K242594

Device Name
DEEPECHO

Indications for Use *(Describe)*
DEEPECHO is intended to analyze fetal ultrasound images and clips using machine learning techniques to detect standard biometry views. Upon views detection, DEEPECHO assists in measurements computation of fetal biometric parameters (i.e., head circumference, abdominal circumference, femur length, and bi-parietal diameter).
The device is intended for use by qualified and appropriately trained healthcare professionals as a concurrent reading and measuring aid during the acquisition and interpretation of fetal ultrasound images of patients aged 18 years or older done between the 14th and the 41st weeks of pregnancy.

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 – K242594

1. SUBMITTER INFORMATION

Applicant:	DeepEcho
Address	555 East Loockerman Street; Dover, DE USA 19901
Contact:	Youssef Bouyakhf
Phone:	+447767643525
Email:	youssef.bouyakhf@deepecho.io

2. CORRESPONDENT INFORMATION

Contact:	Youssef Bouyakhf
Title:	Chief Executive Officer
Firm:	DeepEcho

3. DATE PREPARED: May 21, 2025

4. DEVICE INFORMATION

Device Name:	DEEPECHO
Common Name:	Fetal ultrasound analysis software
Regulation Number:	892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Primary Product Code:	IYN
Regulatory Class:	II
Secondary Product Codes:	IYO, QIH

5. PREDICATE AND REFERENCE DEVICES INFORMATION

Primary Predicate Device Name:	SonioDetect
510(k) Number:	K230365
Manufacturer:	IYN

Reference Device Name:	G8 (specifically the Biometry Assist feature)
510(k) Number:	K223387
Manufacturer:	Samsung Medison Co., Ltd.

6. DEVICE DESCRIPTION

DEEPECHO is a cloud-based standalone software as a medical device (SaMD) that helps qualified healthcare professionals in the assessment of obstetrical images.

The device is intended for use by qualified and appropriately trained healthcare professionals, including but not limited to: radiologists, obstetricians, sonographers, maternal and fetal medicine specialists, obstetricians and gynecologists, as well as fetal surgeons. The device's application is intended for pregnant patients aged 18 years and older between the 14th and the 41st weeks of pregnancy.

DEEPECHO takes as an input either Digital Imaging and Communications in Medicine (DICOM) images or a live fetal ultrasound image streaming from ultrasound scanners. When DEEPECHO is in use, it allows healthcare professionals to browse fetal ultrasound images, identify views (cephalic, abdominal, and femoral) and suggest a placement for calipers on fetal ultrasound images of the identified views and compute biometrical measurements of the latter (HC (Head Circumference), BPD (Bi-parietal Diameter), FL (Femur Length), AC (Abdominal Circumference), GA (Gestational Age), EFW (Estimated Fetal Weight)).

When DEEPECHO is used during real time (i.e., during the examination) the device receives real-time image streaming from an ultrasound machine and can be used to identify views (cephalic, abdominal, and femoral), and suggests a placement for calipers. These Ultrasound images are acquired using an HDMI cable that is plugged into the local device (e.g., computer, tablet) running DEEPECHO, through an HDMI to USB Video Capture. Note that the device cannot compute measurements in real time as the real time data received from the ultrasound machine is a live stream video and not in a DICOM format. DICOM data is necessary to automatically compute biometrical measurements.

Additionally, DEEPECHO handles patient and exam management by allowing healthcare professionals to create, update, and archive records. When DICOM files are uploaded post-examination, the software either links the exam to an existing patient record or automatically generates a new one from the DICOM files' metadata. It enables healthcare professionals to track a patient's history, including exams, reports, and all information directly inputted to the platform.

7. INDICATIONS FOR USE

DEEPECHO is intended to analyze fetal ultrasound images and clips using machine learning techniques to detect standard biometry views. Upon views detection, DEEPECHO assists in measurements computation of fetal biometric parameters (i.e., head circumference, abdominal circumference, femur length, and bi-parietal diameter).

The device is intended for use by qualified and appropriately trained healthcare professionals as a concurrent reading and measuring aid during the acquisition and interpretation of fetal ultrasound images of patients aged 18 years or older done between the 14th and the 41st weeks of pregnancy.

510(k) Summary – K242594

8. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the intended use and the technological characteristics of the subject device and predicate device.

Table 1: Comparator Table for Subject and Predicate Devices

Category	Proposed Device (DEEPECHO)	Primary Predicate Device (Sonio Detect)	Reference Device (Biometry Assist feature in the V8 ultrasound system)
510(k) Number	K242594	K230365	K223387
Applicant	DeepEcho	Sonio	Samsung Medison Co.
Device Name	DEEPECHO	Sonio Detect	Biometry Assist feature in the V8 ultrasound system
Classification Regulation	892.1550 - Accessory to Ultrasonic Pulsed Doppler Imaging System 892.1560 - Accessory to Ultrasonic Pulsed Echo Imaging System 892.2050 - Medical Image Management and Processing System	892.1550 - Accessory to Ultrasonic Pulsed Doppler Imaging System 892.1560 - Accessory to Ultrasonic Pulsed Echo Imaging System 892.2050 - Medical Image Management and Processing System	892.1550 - Ultrasonic Pulsed Doppler Imaging System 892.1560 - Ultrasonic Pulsed Echo Imaging System 892.1570 - Diagnostic Ultrasound Transducer
Product Code	IYN (Primary), IYO, QIH (Secondary)	IYN (Primary), IYO, QIH (Secondary)	IYN, IYO, ITX
Intended Users	Qualified and trained healthcare professionals including radiologists, obstetricians, sonographers, OB/GYNs, maternal and fetal medicine specialists (MFM specialists), and fetal surgeons	Qualified and trained healthcare professionals in a professional prenatal ultrasound imaging environment, including sonographers, MFMs, OB/GYNs, and fetal surgeons	Appropriately trained healthcare professionals qualified for direct use of medical devices
Patient Population	Pregnant patients aged 18 years and older, from 14 to 41 weeks of gestation	Pregnant patients across Trimester 1, Trimester 2, and Trimester 3, from 11 weeks to 37 weeks of gestation	Females of reproductive age
Imaging Modality	Ultrasound	Ultrasound	Ultrasound

510(k) Summary – K242594

Category	Proposed Device (DEEPECHO)	Primary Predicate Device (Sonio Detect)	Reference Device (Biometry Assist feature in the V8 ultrasound system)
Views Detected	Cephalic view, Abdominal view, Femoral view	Transthalamic view, Transventricular view, Transcerebellar view, Four chambers, Profile or Nuchal translucency, Crown rump length, Sagittal spine, Abdominal circumference, Long bone, Upper lip, nose, and nostrils, Left ventricular outflow tract, Right ventricular outflow tract	8 views recommended by the ISUOG and AIUM for biometric measurements and heart assessment.
Measurement Computation	Femur Length (FL), Abdominal circumference (AC), Amniotic Fluid Pocket's Depth, Head circumference (HC), Biparietal Diameter (BPD) Estimated Fetal Weight (EFW), Estimated Gestational Age (EGA)	None	Length measurement (FL, BPD) Ellipse measurement (AC, HC) Nuchal Translucency
Findings	Images labeled with correct views, caliper placement suggestion and measurement for circumference and distance for metrics such as HC, BPD, FL, AC, and examination reports	Images labeled with correct views, quality criteria identified as "Verified" when detected and "Not verified" when not detected	Images labeled with correct view Caliper placement suggestion and measurement for circumference, distance and Nuchal Translucency Editable examination report accessible on the console
Clinical Applications	Fetal/Obstetrics	Fetal/Obstetrics	Fetal/Obstetrics
Real-Time Assistance	Provides real-time identification of views and suggestions for caliper placement.	Primarily focused on verifying the quality criteria of detected views, ensuring that all required views are captured according to standardized protocols	Available on the Samsung V8 for automated view recognition and measurement.

510(k) Summary – K242594

Category	Proposed Device (DEEPECHO)	Primary Predicate Device (Sonio Detect)	Reference Device (Biometry Assist feature in the V8 ultrasound system)
Algorithm Methodology	Artificial Intelligence for biometric measurement computations	Artificial Intelligence for lecture of biometrics and colorimetry for 3D and Doppler	Deep learning-based recognition algorithm
Platform and Accessibility	Cloud-based standalone software accessible from various devices, offering flexibility and ease of integration into different clinical environments	A SaaS solution with edge software requiring installation on a server connected to the ultrasound machine	Embedded in the ultrasound equipment.

DEEPECHO and predicate and reference devices are intended to be used by trained healthcare providers in the analysis of fetal ultrasound images. The devices all use artificial intelligence (AI) and machine learning algorithms to assist healthcare professionals in the interpretation and analysis of these images.

Both DEEPECHO and Sonio Detect are capable of automatically detecting various standard views during fetal ultrasound examinations. The views identified by DEEPECHO are a subset of the views identified by Sonio Detect. Both systems also automatically identify standard fetal ultrasound views.

DEEPECHO and Sonio Detect both generate detailed reports based on the analysis of fetal ultrasound images.

Sonio Detect operates as a Software as a Service (SaaS) solution that requires installation of edge software on a server connected to the same network as the ultrasound machine. In contrast, DEEPECHO is a cloud-based standalone software that can be accessed from various devices, such as laptops, tablets, or desktops, without the need for local server installation. This difference does not raise different types of safety or effectiveness questions, as both deployment methods are commonly used in medical device software.

DEEPECHO differs from Sonio Detect in that it also computes a full set of biometric measurements—FL, AC, BPD, HC, EFW and EGA—which are included directly in its generated report; Sonio Detect does not compute any biometric measurements. In addition, DEEPECHO does not incorporate substructure detection or quality-criteria verification, both of which are provided by Sonio Detect. The Samsung Biometry Assist feature (the secondary reference device) likewise computes biometric measurements but does not automatically derive GA or EFW—users must select one of several well-established formulas to calculate those metrics.

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Software

Software was evaluated for a basic documentation level as recommended in the 2023 FDA guidance document *Content of Premarket Submissions for Device Software Functions* and software verification and validation data was performed.

Performance Testing

DeepEcho performed a stand-alone assessment comparing the performance of the DEEPECHO software to a ground truth of annotations by qualified experts.

Sample Size and Data Source

The bench testing dataset consisted of 417 ultrasound studies collected from 15 clinical sites across the United States, Mexico, and Morocco. Following the application of predefined exclusion criteria, including corrupted files and incomplete views, the final analysis population included 397 subjects, contributing a total of 23,544 de-identified 2D grayscale ultrasound images. Clinical sites included both tertiary maternal-fetal medicine practices and community-based health settings.

Relationship Between Patients and Images

Each subject contributed multiple images, including standard fetal biometry planes (biparietal diameter, head circumference, abdominal circumference, femur length) and non-standard views. Each image was independently reviewed by three ARDMS-certified sonographers with a minimum of five years of clinical ultrasound experience.

Demographics

The population included subjects with a mean maternal age of 29.4 years (range: 15–56) and a mean BMI of 26.8 (range: 17.5–52.5). The racial and ethnic distribution was as follows: 44% White non-Hispanic, 24% Hispanic/Latino, 13.3% Black non-Hispanic, 12.3% Asian, 4.5% Pacific Islander, and 1.9% American Indian or Alaskan Native.

Ultrasound Equipment and Protocols

DEEPECHO was only validated with the following ultrasound systems: Butterfly iQ3, GE Voluson (S8, S10, E6), Clarius HD3, and Philips IU22 and HD7. Image acquisition occurred during second and third trimester exams. All data were stored in DICOM, MP4 and PNG formats. Images from first trimester exams, Doppler imaging, and 3D acquisitions were excluded. No standardized acquisition protocol was enforced across sites.

Truthing Process (Reference Standard Derivation)

All images were annotated using the CVAT platform by three independent ARDMS-certified sonographers with at least five years of experience. For continuous measurement endpoints, the ground truth was calculated as the arithmetic mean of three independent caliper placements. For classification endpoints, ground truth was based on unanimous agreement across reviewers. Inter-reader agreement for continuous outcomes exceeded ICC > 0.99.

Dataset Independence

No training data, patients, or clinical sites overlapped with the test dataset. Training data were obtained from two Roshan MFM clinics in New York City and selected sites in Morocco. Test data were acquired from separate sites in the United States, Mexico, and Morocco, including Seattle (WA), Garden City (NY), Union (NJ), Honesdale (PA), Chiapas (Mexico), and Casablanca (Morocco).

Summary Test Results

There were 6 primary endpoints in the DEEPECHO trial comparing DEEPECHO to ground truth measurements:

1. Comparison of femur length
2. Comparison of head circumference
3. Comparison of abdominal circumference
4. Comparison of biparietal diameter
5. Sensitivity of each view identification
6. Specificity of each view identification

The first four endpoints are concerned with accuracy of continuous measurements, Deming regression was performed to compare the DEEPECHO versus reader measurements.

Results are shown below.

Table 2: Primary Endpoints #1 - #4 Results

Variable	N	Intercept		Slope	
		Point Estimate	95% CI	Point Estimate	95% CI
Femur Length	431	0.003	(-0.020, 0.025)	0.969	(0.966, 0.973)
Head Circumference	858	-.360	(-0.462, -.0258)	1.026	(1.022, 1.031)
Abdominal Circumference	499	-.017	(-0.101, 0.065)	1.017	(1.013, 1.021)
Biparietal Diameter	858	-.165	(-0.203, -0.125)	1.020	(1.015, 1.025)

Primary endpoints #5 and #6 evaluate the sensitivity and specificity of DEEPECHO in detecting anatomical views. To account for intra-subject correlation due to multiple observations per subject, a blockwise bootstrap method was used, with the subject as the resampling unit. The resulting point estimates reflect sample proportions, and the corresponding two-sided 95% confidence intervals were derived using this non-parametric approach.

Table 3: Primary Endpoints #5 and #6 Results

Endpoint of Interest		Statistics	
		n/N	Point Estimate (95% CI)*
Abdominal View	Sensitivity	442/508	86.9% (83.8% - 89.7%)
	Specificity	7107/7340	96.8% (96.4% - 97.2%)
Cephalic View	Sensitivity	992/1010	98.2% (97.4% - 99%)
	Specificity	6482/6838	94.8% (94.2% - 95.3%)
Femoral View	Sensitivity	415/452	91.8% (89% - 94.2%)
	Specificity	7204/7396	97.4% (97% - 97.8%)

*Confidence intervals were calculated using blocked bootstrapping

Worst-case analysis

A worst-case analysis was performed by imputing missing data as failures, based on the average number of observations per subject. After applying this conservative approach, the sensitivity and specificity for each anatomical view were recalculated. For the **abdominal view**, sensitivity was 82.7% (95% CI: 79.0%–85.8%) and specificity was 92.1% (95% CI: 91.4%–92.5%). For the **cephalic view**, sensitivity was 93.4% (95% CI: 91.5%–94.8%) and specificity was 90.2% (95% CI: 89.4%–90.6%). For the **femoral view**, sensitivity was 87.6% (95% CI: 83.5%–90.2%) and specificity was 92.7% (95% CI: 91.9%–93.2%).

Subgroup Analysis

Subgroup analyses were conducted to assess performance of view identification across maternal age, gestational age, BMI, racial/ethnic groups, acquisition sites, ultrasound system manufacturers, image types, image resolution, and operator image quality. For the **cephalic view**, both sensitivity and specificity remained high across all subgroups, with sensitivity typically above 95% and specificity above 93%. For the **femoral view**, sensitivity was also robust, typically exceeding 90%, and specificity remained above 95% across subgroups. In cases where point estimates were lower, this was primarily attributable to small denominators. Importantly, analyses stratified by ultrasound system type, image quality, and operator-assessed image quality showed no evidence of performance degradation.

Table 4: View Identification Primary Endpoint by Gestational Age Subgroups and Per Anatomical View

Anatomical View	Measurement	<= 28 weeks	> 28 weeks
Abdominal	Sensitivity	180/220 (81.8%) [0.761 - 0.867]	221/233 (94.8%) [0.912 - 0.973]

Anatomical View	Measurement	<= 28 weeks	> 28 weeks
	Specificity	4576/4698 (97.4%) [0.969 - 0.978]	2123/2227 (95.3%) [0.944 - 0.962]
Cephalic	Sensitivity	564/580 (97.2%) [0.956 - 0.984]	367/369 (99.5%) [0.981 - 0.999]
	Specificity	4093/4338 (94.4%) [0.936 - 0.95]	1995/2091 (95.4%) [0.944 - 0.963]
Femoral	Sensitivity	174/197 (88.3%) [0.83 - 0.925]	199/206 (96.6%) [0.931 - 0.986]
	Specificity	4580/4721 (97%) [0.965 - 0.975]	2211/2254 (98.1%) [0.974 - 0.986]

Table 5: View Identification Primary Endpoint by BMI Subgroups and Per Anatomical View

Anatomical View	Measurement	18.5 - 25	25 - 30	30 - 35	35 - 40	> 40
Abdominal	Sensitivity	39/48 (81.3%) [0.674 - 0.911]	44/46 (95.7%) [0.852 - 0.995]	17/17 (100%) [0.805 - 1]	6/7 (85.7%) [0.421 - 0.996]	3/4 (75%) [0.194 - 0.994]
	Specificity	903/926 (97.5%) [0.963 - 0.984]	514/532 (96.6%) [0.947 - 0.98]	166/171 (97.1%) [0.933 - 0.99]	80/83 (96.4%) [0.898 - 0.992]	43/45 (95.6%) [0.849 - 0.995]
Cephalic	Sensitivity	132/133 (99.2%) [0.959 - 1]	86/87 (98.9%) [0.938 - 1]	23/23 (100%) [0.852 - 1]	13/14 (92.9%) [0.661 - 0.998]	7/7 (100%) [0.59 - 1]
	Specificity	807/841 (96%) [0.944 - 0.972]	475/491 (96.7%) [0.948 - 0.981]	156/165 (94.5%) [0.899 - 0.975]	73/76 (96.1%) [0.889 - 0.992]	40/42 (95.2%) [0.838 - 0.994]
Femoral	Sensitivity	32/34 (94.1%) [0.803 - 0.993]	34/34 (100%) [0.897 - 1]	12/12 (100%) [0.735 - 1]	5/5 (100%) [0.478 - 1]	4/4 (100%) [0.398 - 1]
	Specificity	914/940 (97.2%) [0.96 - 0.982]	535/544 (98.3%) [0.969 - 0.992]	174/176 (98.9%) [0.96 - 0.999]	83/85 (97.6%) [0.918 - 0.997]	45/45 (100%) [0.921 - 1]

Table 6: View Identification Primary Endpoint by Manufacturer Subgroups and Per Anatomical View

Anatomical View	Measurement	Butterfly	Clarius	General Electric	Philips Medical Systems
Abdominal	Sensitivity	28/42 (66.7%) [0.505 - 0.804]	8/9 (88.9%) [0.518 - 0.997]	252/295 (85.4%) [0.809 - 0.892]	154/162 (95.1%) [0.905 - 0.978]
	Specificity	77/77 (100%) [0.953 - 1]	155/167 (92.8%) [0.878 - 0.962]	5484/5628 (97.4%) [0.97 - 0.978]	1386/1463 (94.7%) [0.935 - 0.958]
Cephalic	Sensitivity	37/37 (100%) [0.905 - 1]	13/13 (100%) [0.753 - 1]	630/635 (99.2%) [0.982 - 0.997]	312/325 (96%) [0.933 - 0.979]
	Specificity	82/82 (100%) [0.956 - 1]	141/163 (86.5%) [0.803 - 0.913]	5088/5288 (96.2%) [0.957 - 0.967]	1166/1300 (89.7%) [0.879 - 0.913]
Femoral	Sensitivity	33/40 (82.5%) [0.672 - 0.927]	8/11 (72.7%) [0.39 - 0.94]	207/216 (95.8%) [0.922 - 0.981]	167/185 (90.3%) [0.851 - 0.941]
	Specificity	79/79 (100%) [0.954 - 1]	152/165 (92.1%) [0.869 - 0.957]	5590/5707 (97.9%) [0.975 - 0.983]	1378/1440 (95.7%) [0.945 - 0.967]

10. CONCLUSION

The results of the performance testing described above demonstrate that the DEEPECHO software is as safe and effective as the predicate device and supports a determination of substantial equivalence.