September 27, 2022

Philips Ultrasound LLC
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K222648
Trade/Device Name: 5000 Compact Series Ultrasound Systems (Ultrasound System 5500 G, Ultrasound System 5500 P, Ultrasound System 5500 W, Ultrasound System 5500 CV, Ultrasound System 5300 G, Ultrasound System 5300 P, Ultrasound System 5300 W)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 31, 2022
Received: September 1, 2022

Dear Prithul Bom:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222648

Device Name
5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5500CV, Ultrasound System 5300G, Ultrasound System 5300P, Ultrasound System 5300W)

Indications for Use *(Describe)*
The 5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5500CV, Ultrasound System 5300G, Ultrasound System 5300P, Ultrasound System 5300W) are intended for diagnostic Ultrasound imaging in B (or 2D), 3D/4D, Color Doppler, Continuous Wave Doppler, Pulse Wave Doppler, Tissue Doppler, M-mode (including anatomical M-mode), Harmonics (Tissue and Contrast), Color Power Angio (CPA), and Combined modes.

5000 Compact series is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Abdominal, Adult Cephalic, Cardiac Adult, Cardiac Pediatric, Carotid, Cerebral vascular, Fetal Echo, Fetal/Obstetric, Gynecological, Intra-operative (Vascular), Lung, Musculoskeletal (conventional), Musculoskeletal (superficial), Neonatal Cephalic, Ophthalmic, Pediatric, Peripheral Vessel, Small Organs (breasts, testicles, thyroid), Transesophageal (cardiac), Trans-rectal, Trans-vaginal, Urology.

The clinical environments where the 5000 Compact Series Ultrasound Systems can be used are: hospitals, surgery centers, clinics, physicians' office, diagnostic centers, critical care and emergency room environments, point-of-care clinical settings for diagnosis of patients.

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. However, nothing stated in the user information reduces the user's responsibility for sound clinical judgment and best clinical procedure. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed.

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.

5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5500CV, Ultrasound System 5300G, Ultrasound System 5300P, Ultrasound System 5300W)

This summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92

1. Submitter's name, address, telephone number, contact person

Manufacturer: Philips Ultrasound LLC
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact Person: Shilpa Rapaka
Senior Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, WA 98021-8431
Phone: 203 213 6862

Secondary Contact: Tamara Daniels
Senior Regulatory Affairs Manager
22100 Bothell Everett Hwy
Bothell, WA 98021-8431
Phone: 203 213 6862

Date Prepared: September 27, 2022

2. Name of the device, including the trade of proprietary name if applicable, the common or usual name, and the classification name, if known:

Proprietary Name: 5000 Compact Series Ultrasound Systems
Marketed under the following models:
Ultrasound System 5500G
Ultrasound System 5500P
Ultrasound System 5500W
Ultrasound System 5500CV
Ultrasound System 5300G
Ultrasound System 5300P
Ultrasound System 5300W

Common Names: Ultrasonic pulsed doppler imaging system
Ultrasonic pulsed echo imaging system
Diagnostic ultrasonic transducer

Regulation Description:

Classification Name	21 CFR Section	Product Code
System, imaging, pulsed doppler, ultrasonic	892.1550	IYN
System, imaging, pulsed echo, ultrasonic	892.1560	IYO
Transducer, ultrasonic, diagnostic	892.1570	ITX

As stated in 21 CFR parts 892.1550, 892.1560, and 892.1570, each of these generic types of devices have been classified as Class II.

Device Class: Class II

3. Indications for Use

The 5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5500CV, Ultrasound System 5300G, Ultrasound System 5300P, Ultrasound System 5300W) are intended for diagnostic Ultrasound imaging in B (or 2D), 3D/4D, Color Doppler, Continuous Wave Doppler, Pulse Wave Doppler, Tissue Doppler, M-mode (including anatomical M-mode), Harmonics (Tissue and Contrast), Color Power Angio (CPA), and Combined modes.

5000 Compact series is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Abdominal, Adult Cephalic, Cardiac Adult, Cardiac Pediatric, Carotid, Cerebral vascular, Fetal Echo, Fetal/Obstetric, Gynecological, Intra-operative (Vascular), Lung, Musculoskeletal (conventional), Musculoskeletal (superficial), Neonatal Cephalic, Ophthalmic, Pediatric, Peripheral Vessel, Small Organs (breasts, testicles, thyroid), Transesophageal (cardiac), Trans-rectal, Trans-vaginal, Urology.

The clinical environments where the 5000 Compact Series Ultrasound Systems can be used are: hospitals, surgery centers, clinics, physicians' office, diagnostic centers, critical care and emergency room environments, point-of-care clinical settings for diagnosis of patients.

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. However, nothing stated in the user information reduces the user's responsibility for sound clinical judgment and best clinical procedure. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed.

4. Device Description Summary

The proposed Philips 5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5500CV, Ultrasound System 5300G, Ultrasound System 5300P, Ultrasound System 5300W) are general purpose, compact, battery or alternating current (AC) powered, software controlled, diagnostic ultrasound

systems. The ultrasound system is housed in a portable, laptop-style chassis. The ultrasound system function is to acquire ultrasound data and to display the data in various modes of operation. The ultrasound system components include the monitor, control panel, transducer receptacles, ECG/physio receptacles, and AC adapter/battery charger. The ultrasound system can be attached to an optional cart. The cart height is adjustable to accommodate a range of operator heights and operating positions. The cart has wheels for maneuverability and may provide isolated power for system and peripheral components (such as black and white image printer or a report printer).

The 5000 Compact Series Ultrasound Systems comprises of different configurations which differ in terms of features, transducer options, and license options (features available as purchasable options in addition to the standard features available in the system. The types of options available include clinical options, QLAB Advanced Quantification Software, protocols, imaging capabilities, connectivity capabilities, etc.). The 5500G is the primary configuration with the most available capabilities. Identical software architecture is used in all configurations and all configurations are derived from a common codebase. Similarly, the hardware is same for all configurations. All the 5000 Compact Series Ultrasound System configurations are compatible with existing Philips transducers cleared in Philips Affiniti Ultrasound System (K200304). 5500 Compact Series POC (point-of-care) configurations leverage POC features from the CX50 platform (K162329) to enable efficient POC ultrasound capability.

5. Substantially Equivalent Devices

Primary Predicate Device: Philips Affiniti Ultrasound System (K200304)

Reference Device: Philips CX 50 Ultrasound Systems (K162329)

6. Technological Comparison to Predicate Devices

The proposed 5000 Compact Series Ultrasound Systems are substantially equivalent to the currently marketed predicate devices. The following is an overview of the similarities between the proposed 5000 Compact Series Ultrasound System and the currently marketed predicate and reference devices.

- The systems employ the same fundamental scientific technology for imaging, doppler functions, and signal processing and have the same grayscale and doppler capabilities
- The systems are all are indicated for diagnostic ultrasonic imaging and fluid flow analysis for use by the same type of users in the same type of use environments
- The systems have the same clinical intended uses and indications for use
- The systems have the same imaging modes
- The transducers are identical
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device

- The systems have acoustic power levels which are within the Track 3 FDA limits
- The systems have similar capability in terms of performing measurements, capturing digital images, reviewing, and reporting studies
- The systems have been designed and manufactured to the same electrical and physical safety standards manufactured under equivalent quality systems

A comparison of the subject 5000 Compact Series Ultrasound Systems and the predicate and reference devices is shown in **Table 8-1** below.

Table 8-1. Comparison of the proposed 5000 Compact Series Ultrasound Systems to the currently marketed predicate and reference devices

Standard Feature/ Technology Characteristics	**Proposed Philips 5000 Compact Series Ultrasound Systems**	**Predicate EPIQ/Affiniti Ultrasound System (K200304)**	**Reference CX50 Ultrasound Systems (K162329)**
Classification	Class II	Class II	Class II
Product Codes	IYN IYO ITX	IYN IYO ITX	IYN IYO ITX
Classification Regulation Numbers	21 CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570	21 CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570	21 CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570
Indications for Use and Modes of Operation	Abdominal, Adult Cephalic, Cardiac Adult, Cardiac Pediatric, Carotid, Cerebral vascular, Fetal Echo, Fetal/Obstetric, Gynecological, Intra-operative (Vascular), Lung, Musculoskeletal (conventional), Musculoskeletal (superficial), Neonatal Cephalic, Ophthalmic, Pediatric, Peripheral Vessel, Small Organs (breasts, testicles, thyroid),	Fetal/Obstetric, Abdominal, Intraoperative (Vascular), Intraoperative (Cardiac), Pediatric, Small Organ (Breast, Thyroid, Testicle), Cephalic (Neonatal), Cephalic (Adult), Transrectal, Transvaginal Musculoskeletal (Conventional), Musculoskeletal (Superficial) Gynecological, Other: Urology, Cardiac Adult, Cardiac Pediatric, Transesophageal (Cardiac), Cardiac other (Fetal),	Ophthalmic, Intracardiac echo, Intraoperative, Laparoscopic, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Neonatal Cephalic, Trans-vaginal, Musculoskeletal, Gynecological, Cardiac Adult, Cardiac pediatric, Trans-Esophageal. (Cardiac), Peripheral Vessel, Other (Carotid), Trans-rectal **Modes of Operation**: Sparq B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave

	Transesophageal (cardiac), Trans-rectal, Trans-vaginal, Urology **Modes of Operation**: B (or 2D), 3D/4D, Color Doppler, Continuous Wave Doppler, Pulse Wave Doppler, Tissue Doppler, M-mode (including anatomical M-mode), Harmonics (Tissue and Contrast), Color Power Angio (CPA), Combined modes	Peripheral Vessel, Cerebral Vascular, **Modes of Operation:** B (2D), M, PWD, CWD, Color Doppler, Combined (B+PWD, B+Color, B+Amplitude, B+M, B+M+Color, B+Color+PWD, B+Amplitude+PWD, B+CWD; B+Color+CWD; B+Amplitude+CWD), SonoCT, Imaging for guidance of biopsy, Panoramic Imaging, Color Power Angio (CPA), Harmonic Imaging, Contrast, 3D/4D Imaging, XRES	Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) CX50 B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes
Transducers	No new transducers introduced as part of 5000 Compact Series. All transducers that are part of the 5000 Compact Series are already cleared in K200304 or K162329.	Affiniti 3D9-3v, C5-1, C6-2, C8-5, C9-2, C9-4V, C10-4ec, D2cwc, D2tcd, D5cwc, BP10-5ec, eL18-4, L12-3, L12-3ERGO, L12- 4, L12-5 50, L15-7io, L18-5, S4-2, S5-1 S7-3t, S8-3, S12-4, V6-2, VL13-5, X7-2t, V9-2, mC7-2 EPIQ C5-1, C8-5, C9-2, C10-3v, C10-4ec, D2cwc, D5cwc, eL18-4, L12-3, L12-5 50, L15-7io, L18-5, S5-1, S7-3t, S8-3, S8-3t, S12-4, V6-2, X7-2t, X8-2t, D2tcd, X5-1, X6-1, VL13-5, X7-2, X8-2ti, XL14-3, 3D9-3v, V9-2, mC7-2, mC12-3	C5-1 C8-5 C9-3io C9-3v C10-3v D2cwc D5cwc L10-4 lap L12-3 L12-5 50 L15-7io S5-1 S8-3 S12-4 S7-3t X7-2t C6-2 C9-4v L12-4 S4-2

Power Supply	Same	Rechargeable lithium ion batteries, AC Adapter	Rechargeable lithium ion batteries, AC Adapter
Optional Accessories/Peripherals	Various hardcopy, recording and printing products, black-and-white image printer, USB storage devices, Biopsy guides, Footswitch, Barcode scanner	Various hardcopy, recording and printing devices: digital video recorder (DVR), digital video disc (DVD), report printer, thermal printer (B/W, color), USB, PercuNav Instruments, Biopsy guides, Footswitch	Various hardcopy, recording and printing devices: report printer, DVD, USB, Biopsy guides, Footswitch
Form factor	Portable Laptop that can be placed on a mobile cart	Cart based, with an articulating monitor arm	CX50= Portable Laptop that can be placed on a mobile cart Sparq= Cart based, with an articulating monitor arm
Battery Life	System operates via internal battery or AC power. System battery supports up to 30 min scanning. Extended battery up to 2 hours with optional batteries	System operates on AC power. A battery is provided to put the system in Sleep mode for up to 30 minutes allowing the system to be transported to a new location without powering down the system.	The system operates via an internal battery or AC Power. System battery supports up to 30 minute scanning.
Wireless Network Functions	Integrated on PC module Wired and wireless	Integrated on PC module Wired and wireless	Wired Ethernet Wireless USB Adapter
Software Features	Imaging Modes Patient Data Entry Patient Database and Storage Generic Measurement Tools Analysis and Calculation Packages Annotations	Imaging Modes Patient Data Entry Patient Database and Storage Generic Measurement Tools Analysis and Calculation Packages Annotations	Imaging Modes Patient Data Entry Patient Database and Storage Generic Measurement Tools Analysis and Calculation Packages Annotations
Clinical Options	Abdomen Clinical Option Adult Cardiology Clinical Option	Abdomen Clinical Option Adult Cardiology Clinical Option	Abdomen Clinical Option Adult Cardiology Clinical Option

	Advanced Capabilities Limited Clinical Option Breast Clinical Option Fetal Echo Clinical Option GYN Clinical Option Musculoskeletal Clinical Option OB Clinical Option Pediatric Cardiology Clinical Option Pediatric GI Clinical Option Small Parts Clinical Option TCD Clinical Option Urology Clinical Option Vascular Clinical Option POC Clinical Option	Advanced Capabilities Limited Clinical Option Breast Clinical Option Fetal Echo Clinical Option GYN Clinical Option Musculoskeletal Clinical Option OB Clinical Option Pediatric Cardiology Clinical Option Pediatric GI Clinical Option Small Parts Clinical Option TCD Clinical Option Urology Clinical Option Vascular Clinical Option	Fetal Echo Clinical Option GYN Clinical Option Musculoskeletal Clinical Option OB Clinical Option Pediatric Cardiology Clinical Option Pediatric GI Clinical Option Small Parts including Breast Clinical Option Cerebrovascular including TCD Clinical Option Vascular Clinical Option Peripheral Vascular Clinical Option Regional Anesthesia Clinical Option Acute Care Clinical Option
Performance Options	Advanced Cardiac UI Anatomic Mmode Auto Doppler Auto Scan iScan Contrast Card Contrast Card Low MI Contrast GI Freehand 3D High Q MaxVue MicroFlow Imaging Netlink DICOM Ultrasound Query Retrieve Multi-Modality Query Retrieve Panoramic 2D Smart Exam Stress Protocol	Advanced Cardiac UI Anatomic Mmode Auto Doppler Auto Scan iScan Contrast Card Contrast Card Low MI Contrast GI Freehand 3D High Q MaxVue MicroFlow Imaging Netlink DICOM Ultrasound Query Retrieve Multi-Modality Query Retrieve Panoramic 2D Smart Exam Stress Protocol	Anatomic M mode Auto Doppler Auto Scan iScan Contrast Card Contrast GI Freehand 3D High Q Netlink DICOM Ultrasound Query Retrieve Smart Exam Stress Protocol
System Options	3D Color 4D Imaging aBiometry Assist aReveal	3D Color 4D Imaging aBiometry Assist aReveal	3D Color Live 3D Imaging – TEE only

	Barcode Scanner SW Digital Navigation Link FlexVue Transducer Element Check Needle Visualization Physio SW Strain Elastography Option STIC TrueVue Government Security SafeGuard Security Plus	Barcode Scanner SW Digital Navigation Link FlexVue Transducer Element Check Needle Visualization Physio SW Strain Elastography Option STIC TrueVue Government Security SafeGuard Security Plus	Digital Navigation Link Transducer Element Check Needle Visualization Physio SW Strain Elastography Option Government Security SafeGuard Security Plus
Quantification Options	a2DQ AutoStrain LV FHN GI 3DQ IMT MVI ROI Strain Elastography Analysis Strain Elastography Quantification Strain Q	a2DQ AutoStrain LV FHN GI 3DQ IMT MVI ROI Strain Elastography Analysis Strain Elastography Quantification Strain Q	a2DQ aCMQ MVN GI 3DQ 3DQa IMT MVI ROI
Hardware platform – Related Modules	Physio: ECG, Respiration, Pulse, Phono Side I/O: USB, Display Port Video, Wired Ethernet Monitor - 15.6 inch Landscape LCD	Optical Drive: CD / DVD-RW Physio: ECG, Respiration, Pulse, Phono Side I/O: USB, S-Video, Aux Physio Rear I/O: DisplayPort video, USB, Ethernet Monitor: 21.5 inch LCD	Optical Drive: CD / DVD-RW Physio: ECG, Respiration, Pulse, Phono Side I/O: USB, DVI Video, Aux Physio, Wired Ethernet Monitor: 15.6 inch LCD
Clinical Environments	Hospitals, surgery centers, clinics, physicians' office, diagnostic centers, critical care and emergency room environments, point-of-care clinical settings for diagnosis of patients.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Point-of-care areas in offices, clinical and hospital settings for diagnosis of patients.

7. Safety Considerations

The subject 5000 Compact Series Ultrasound Systems are all Track 3 Devices and comply with the referenced standards as well as the FDA ultrasound guidance document, *Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*, issued on June 27, 2019.

8. Nonclinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed 5000 Compact Series Ultrasound Systems:

- ANSI/AAMI ES 60601-1: Medical electrical equipment. Part 1: General requirements for basic safety and essential performance, 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (consolidated text)
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014
- IEC 60601-1-6 Medical Electrical Equipment Part 1-6, General Requirements for Basic Safety and Essential Performance- Collateral standard: Usability, 2013
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015
- IEC 62304: Medical Device Software – Software life cycle process, 2015
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017-09
- ANSI AAMI ISO 14971: Medical devices- Applications of risk management to medical devices, 2019

Non-Clinical verification testing has been performed addressing system level requirements according to system and design specifications, and risk control measures. Design Control activities to assure the safety and effectiveness of 5000 Compact Series include but are not limited to the following:

- Requirements Review
- Risk Analysis and Management
- Product Specifications
- Design Reviews
- Verification and Validation

Biocompatibility testing is not needed for the proposed 5000 Compact Series Ultrasound Systems as the transducer patient contacting materials and manufacturing processes are not impacted by the introduction of the proposed Philips 5000 Compact Series Ultrasound Systems.

9. Clinical Data

The proposed 5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5500CV, Ultrasound System 5300G, Ultrasound System 5300P, Ultrasound System 5300W) did not require clinical data for determination of substantial equivalence since substantial equivalence was demonstrated based on the following attributes:

- Design features
- Indications for use
- Fundamental scientific technology
- Non-clinical performance testing
- Safety and effectiveness

10. Sterilization

The proposed 5000 Compact Series Ultrasound Systems are not provided sterile.

11. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed 5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5500CV, Ultrasound System 5300G, Ultrasound System 5300P, Ultrasound System 5300W) meet their intended use.

While the predicate, Affiniti, is a standard, cart-based ultrasound system, 5500 Compact Series is a compact, laptop-style system which provides ease of portability for the users. Additionally, 5000 Compact Series POC (point-of-care) configurations leverage POC features from the CX50 platform to enable efficient POC ultrasound capability. These design changes do not significantly affect the use of the device, nor do they introduce any new or significantly modified risks. The differences between the subject device and predicate device do not raise new questions of safety and/or effectiveness. Therefore, the proposed 5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5300G, Ultrasound System 5500CV, Ultrasound System 5300P, Ultrasound System 5300W) is similar to the predicate Philips Affiniti Series Diagnostic Ultrasound Systems in terms of indications for use, design, technological characteristics, modes of operations, safety and effectiveness.