Philips Ultrasound, LLC
Colin Jacob
Principal Regulatory Affairs Specialist
22100 Bothell Everett Hwy.
Bothell, Washington 98021

July 27, 2026

Re: K261211
Trade/Device Name: Philips EPIQ Series Diagnostic Ultrasound System; Philips Affiniti Series Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH, OBJ, LLZ
Dated: April 13, 2026
Received: April 14, 2026

Dear Colin Jacob:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.07.27 08:25:55 -04'00' For

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

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.	K261211 ?

Please provide the device trade name(s). ?

Philips EPIQ Series Diagnostic Ultrasound System;
Philips Affiniti Series Diagnostic Ultrasound System

Please provide your Indications for Use below. ?

EPIQ Indications for Use:

The intended use of EPIQ Ultrasound Diagnostic System is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.

Modes of operation include: B Mode (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, Harmonic Imaging.

The clinical environments where EPIQ Series Diagnostic ultrasound Systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live echo guidance.

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. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Affiniti Indications for Use:

The intended use of Affiniti Series Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

Abdominal, Cardiac Adult, Cardiac Other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.
Modes of operation include: B Mode (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging.

The clinical environments where the Affiniti diagnostic ultrasound systems can be used include clinics,

hospitals, and clinical point-of-care 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.

Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

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)	?

PHILIPS

510(k) Summary

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

510(k) Number: K261211

Date Prepared: 22 July 2026

I. Submitter

Manufacturer Name and Address	Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA
Contact Information	Colin Jacob Principal Regulatory Affairs Specialist 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA colin.jacob@philips.com +1.425.482.8293
Secondary Contact	Benny Lam Director of Regulatory 22100 Bothell Everett Hwy benny.lam@philips.com Bothell, WA 98021-8431 USA +1.240.463.2613

II. Device

Proprietary Name	Philips EPIQ Series Diagnostic Ultrasound System; Philips Affiniti Series Diagnostic Ultrasound System; Philips Collaboration Live
Common Name	Diagnostic Ultrasound System and Transducers; System, Imaging Processing, Radiological

PHILIPS

Regulation Description

Classification Description	21 CFR §	Product Code
Primary		
System, imaging, pulsed doppler, ultrasonic	892.1550	IYN
Secondary		
System, imaging, pulsed echo, ultrasonic	892.1560	IYO
Transducer, ultrasonic, diagnostic	892.1570	ITX
Automated Radiological Image Processing Software	892.2050	QIH
Diagnostic Intravascular Catheter	870.1200	*OBJ
System, image processing, radiological	892.2050	**LLZ

*OBJ is only applicable to EPIQ Series
**LLZ is only applicable to Collaboration Live

Device Class

Class II

Review Panel

Radiology

Predicate Device

(K251651)

- EPIQ Series Diagnostic Ultrasound System;
- Affiniti Series Diagnostic Ultrasound System

Predicate Device Regulation

Classification Description	21 CFR §	Product Code
Primary		
System, imaging, pulsed doppler, ultrasonic	892.1550	IYN
Secondary		
System, imaging, pulsed echo, ultrasonic	892.1560	IYO
Transducer, ultrasonic, diagnostic	892.1570	ITX
Automated Radiological Image Processing Software	892.2050	QIH
Diagnostic Intravascular Catheter	870.1200	*OBJ

*OBJ is only applicable to EPIQ Series

Reference Device (K212777)

- Collaboration Live

Reference Device Regulation

Classification Description	21 CFR §	Product Code
Primary		
System, image processing, radiological	892.2050	LLZ
Secondary		
System, imaging, pulsed echo, ultrasonic	892.1560	IYO
System, imaging, pulsed doppler, ultrasonic	892.1550	IYN

III. Device Description

This 510(k) Premarket Notification supports a software-only modification for the Philips EPIQ and Affiniti Series Diagnostic Ultrasound Systems. These ultrasound platforms use conventional, FDA-cleared diagnostic ultrasound technology and have been cleared in multiple configurations since 2013 (EPIQ) and 2016 (Affiniti). The subject device's software update maintains the systems' intended use, overall system architecture, and underlying technological principles while providing incremental enhancements within previously cleared capabilities.

The EPIQ and Affiniti Systems are general-purpose, software-controlled diagnostic ultrasound devices that acquire, process, and display real-time ultrasound information across standard imaging modes. System configurations typically include:

FDA-cleared System Console:

Houses system electronics, processing hardware, a touch screen, control panel, integral display monitor, and multiple transducer ports.

FDA-cleared Transducer Portfolio:

Supports an existing set of FDA-cleared Philips transducers for clinical applications such as 2D imaging, Doppler and Color Doppler, cardiac, abdominal, obstetric, gynecologic, musculoskeletal, pediatric, and specialty imaging.

No new transducers, acoustic output changes, or hardware modifications are introduced in this submission.

The subject software update introduces performance and usability enhancements within the already cleared capabilities of the systems. The modification does not add new indications for use, new imaging modes, new diagnostic claims, changes to hardware, changes to acoustic output, or modifications to the systems' fundamental operating principles. The software modification includes refinements to existing capabilities, such as:

Tele-ultrasound improvements:

- Removal of support for a legacy desktop client,
- Expanded browser-based client compatibility using modern Chromium-based browsers.

Image-quality refinements:

- Border-enhancement processing improvements,
- Adaptive blending of fundamental frequency components,
- Updated microvascular imaging reconstruction algorithms,

Workflow enhancements:

- Automated frame/cine selection in 2D, Color, and PW modes,
- Additional color post-processing controls,
- User interface and color-map updates,
- Contrast imaging display refinements, and
- OB workflow tools supporting quadrant-based AFI evaluation.

All enhancements function within existing, FDA-cleared imaging modes and do not alter the intended use, diagnostic performance claims, or technological characteristics of the system.

IV. Intended Use & Indications for Use

EPIQ & Affiniti Series Intended Use

The intended use of EPIQ and Affiniti Ultrasound Diagnostic System is diagnostic ultrasound imaging and fluid flow analysis of the human body.

EPIQ Indications for Use:

The intended use of EPIQ Ultrasound Diagnostic System is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.

Modes of operation include: B Mode (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, Harmonic Imaging

The clinical environments where EPIQ Series Diagnostic ultrasound Systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live echo guidance.

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. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Affiniti Indications for Use:

The intended use of Affiniti Series Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

Abdominal, Cardiac Adult, Cardiac Other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.

Modes of operation include: B Mode (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, Harmonic Imaging.

The clinical environments where the Affiniti diagnostic ultrasound systems can be used include clinics, hospitals, and clinical point-of-care 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.

Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Collaboration Live Intended Use

The intended use of Collaboration Live is displaying images for diagnostic viewing and review.

Collaboration Live Indications For Use:

Collaboration Live is indicated for remote console access of the Philips ultrasound system for diagnostic image viewing and review, consultation, guidance, support, and education in real time. Access must be granted by the healthcare professionals operating the ultrasound system. Compliance with the technical and operator requirements specified in the User Manual is required.

It is the responsibility of the healthcare professionals at the remote client to ensure image quality, display contrast, and ambient light conditions are consistent with the generally accepted standards of the clinical application.

V. Comparison of Technological Characteristics with the Predicate

The subject device maintains the same intended use as the predicate device, with no changes to the diagnostic purpose or clinical applications. Both the subject and predicate device are indicated for diagnostic ultrasound imaging and fluid flow analysis and are intended for use by appropriately trained healthcare professionals in the same clinical environments.

The subject device and predicate device share the same FDA device classification and product codes, and they incorporate the same fundamental software architecture, system hardware, and imaging modes. Acoustic output characteristics are equivalent, and all acoustic output levels remain within FDA Track 3 limits and in accordance with IEC 60601-2-37 requirements. The update does not introduce new transducer types, and compatibility with existing cleared transducers remains unchanged. Patient-contacting materials and manufacturing processes are unmodified and continue to meet biocompatibility requirements in accordance with ISO 10993-1.

The subject device introduces software-only modifications that represent refinements to existing image processing, workflow, and visualization capabilities within cleared imaging modes. The technological differences between the subject device and predicate device are summarized below.

Summary of Technological Differences

- Collaboration Live
    - Subject Device: Removes support for a legacy desktop client and expands compatibility to modern Chromium-based browser clients for remote access, display, and interaction with ultrasound imaging sessions.
    - Predicate Device: Supports remote access and tele-ultrasound functionality, including browser-based and/or client-based interaction for diagnostic viewing, consultation, and collaboration.
    - Technological Comparison: Both the subject and predicate device provide tele-ultrasound functionality that enables remote viewing and interaction with ultrasound images. The subject device modifies the client access mechanism by retiring a legacy desktop client and standardizing support on modern browser-based platforms. These changes are limited to interoperability and user access and do not alter image acquisition, transmission principles, data integrity, or visualization algorithms.
- EdgeBoost
    - Subject Device: Provides enhanced boundary delineation in grayscale imaging through refined imaging-processing algorithms that improve visualization of anatomical edges.

- Predicate device: XRes includes existing imaging-processing functions for grayscale enhancement and boundary visualization
- Technological Comparison: Both devices use post-processing of acquired ultrasound signals to enhance image display. The subject device refines existing algorithms without modifying signal acquisition, beamforming, or introducing a new imaging mode.

- Adaptive Fundamental Frequency Blending
  - Subject Device: Implements adaptive blending of fundamental frequency components to optimize image uniformity and contrast.
  - Predicate Device: Utilizes conventional fundamental frequency imaging techniques within established imaging modes.
  - Technological Comparison: The modification refines how existing frequency components are combined during post-processing, without altering acoustic output, transmit/receive behavior, or imaging modes.
- Color Gain Post-Processing
  - Subject Device: Provides additional post-processing control to adjust color flow visualization after acquisition.
  - Predicate Device: Includes standard color Doppler gain and post-processing controls.
  - Technological Comparison: Both devices utilize post-acquisition color signal processing. The subject device expands user control without changing Doppler signal acquisition, processing algorithms, or output characteristics.
- 2D and Color/PW Auto/Cine Select
  - Subject Device: Automatically selects representative frames or cine loops in 2D, Color, and PW Doppler modes to support workflow efficiency.
  - Predicate Device: Supports manual selection and review of cine loops and frames.
  - Technological Comparison: Operates on already acquired image data without modifying acquisition or processing. The feature introduces workflow automation only, with no impact to imaging performance or signal generation.
- SuperRes MVI 2.0
  - Subject Device: Provides refined microvascular imaging reconstruction algorithms to enhance visualization of low-flow vascular structures.

- Predicate Device: Includes existing microvascular imaging capabilities based on similar reconstruction principles.
- Technological Comparison: The update improves reconstruction performance using the same underlying data inputs and processing framework, with no changes to acoustic output, acquisition methods, or imaging modes.

- Contrast Enhanced Ultrasound Workflow
  - Subject Device: Introduces workflow refinements and display improvements for contrast-enhanced ultrasound (CEUS) imaging.
  - Predicate Device: Supports CEUS imaging within established imaging modes and workflows.
  - Technological Comparison: Enhancements are limited to workflow and visualization improvements and do not modify contrast imaging principles, signal acquisition, or processing methods.
- Quad AFI
  - Subject Device: Provides quadrant-based amniotic fluid index (AFI) workflow tools to support obstetric assessment.
  - Predicate Device: Includes standard measurement and obstetric workflow capabilities.
  - Technological Comparison: The feature organizes and presents measurements derived from existing imaging data; no new signal acquisition, processing, or diagnostic claims are introduced.
- Updated User Interface
  - Subject Device: Includes updates to user interface elements, display layouts, and color mapping to improve usability.
  - Predicate Device: Includes an established graphical user interface for ultrasound system operation.
  - Technological Comparison: Changes are limited to user interface presentation and do not affect underlying imaging algorithms, data processing, or system performance.

All technological changes introduced through this software-only update consist of performance, workflow, interoperability, and usability enhancements within previously cleared system capabilities. These modifications do not raise new or different questions of safety or effectiveness. Verification, validation, usability testing, cybersecurity evaluation, and risk management activities performed in accordance with IEC 62304 and ISO 14971 confirm that the updated system continues to perform safely and effectively. Therefore, the subject device is substantially equivalent to the predicate device.

VI. Safety Considerations

The proposed EPIQ and Affiniti Series Diagnostic Ultrasound Systems, including software functionalities, and compatible transducers 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 (*February 2023).

VII. Nonclinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed subject device:

- IEC 62304:2006+AMD1:2015 Medical Device Software – Software life cycle process
- IEC 62366-1:2015+AMD1:2020 Medical devices – Application of usability engineering to medical devices
- ISO 14971:2019 Medical devices – Application of risk management to medical devices

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 the subject device include but are not limited to the following:

- Requirements Review
- Risk Analysis and Risk Management Review
- Product Specification Review
- Design Review

VIII. Clinical Data

There was no clinical investigation needed for this premarket submission of the EPIQ and Affiniti Series Diagnostic Ultrasound Systems, or Collaboration Live.

IX. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

X. Conclusion

The proposed software update for the Philips EPIQ and Affiniti Series Diagnostic Ultrasound Systems has been evaluated for substantial equivalence in accordance with the FDA guidance document "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*," (issued 28 July 2014).

- The predicate device is legally marketed.
- Intended use and indications for use remain unchanged.
    - The software update does not alter the diagnostic purpose or clinical applications of the systems.

- Technological characteristics remain consistent with the predicate.
    - Core system architecture, imaging modes, acoustic output characteristics, and transducer compatibility remain unchanged.
- Only software-based enhancements were introduced.
    - The update includes workflow refinements, user interface improvements, tele-ultrasound capabilities, and incremental image quality optimizations.
    - These modifications do not change the device's foundational operating principles.
- Technological differences do not raise new questions of safety or effectiveness.
    - All updated features were evaluated using Philips' risk management process in accordance with ISO 14971.
    - Any new or modified risks were fully characterized and mitigated using established risk control measures.
    - No new or different questions of safety or effectiveness are introduced compared with the predicate device.
- Verification and validation confirm continued safe and effective performance.
    - Software verification testing, regression testing, usability evaluation, cybersecurity assessment, and system-level validation demonstrate that the updated systems meet all specifications and continue to perform safely and effectively.

Based on the FDA's substantial equivalence framework, the updated software configuration is substantially equivalent to the predicate device with respect to intended use, technological characteristics, safety, and effectiveness.