June 15, 2026

Anumana, Inc.
% Michael Billig
Regulatory Consultant for Anumana, Inc., Executive Advisor, Veranex, Inc.
Veranex, Inc.
5420 Wade Park Blvd., Suite 204
Raleigh, North Carolina 27607

Re: K260300
Trade/Device Name: WatchMate Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 8, 2026
Received: May 11, 2026

Dear Michael Billig:

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,

for

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software Team
DHT8B: 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.	K260300

Please provide the device trade name(s).

WatchMate Software

Please provide your Indications for Use below.

WatchMate Software enables visualization and measurement of structures of the heart and vessels for pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure.
To facilitate the above, WatchMate Software provides general functionality such as:

- 3D reconstruction of the left atrial appendage (LAA) from trans-esophageal echocardiogram images of the left atrial appendage
- Visualization and image reconstruction, including 2D review and 3D rendering
- Measurement and annotation tools

The results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment.

WatchMate Software's intended patient population is comprised of adult patients.

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)

510(k) Summary

510(k) Notification K260300

GENERAL INFORMATION [807.92(a)(1)]

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Date Prepared: May 29, 2026

DEVICE INFORMATION [807.92(A)(2)]

Classification: 21 CFR 892.2050 – Medical image management and processing system; Class II

Product Code: Primary Product Code: QIH

Trade Name: WatchMate Software

Generic/Common Name: WatchMate TEE

PREDICATE DEVICE(S) [807.92(A)(3)]

- Predicate Device: Circle Cardiovascular Imaging, Inc. - TruPlan Computed Tomography (CT) Imaging Software (K222593)
- Reference Device 1: Philips Ultrasound, Inc. - 3D Auto LAA (K201352)
- Reference Device 2: Nesa Medtech Private Limited - Fibroid Mapping Reviewer Application (FMRA) (K222683)

510(k) Summary

DEVICE DESCRIPTION [807.92(A)(4)]

The WatchMate Software (Version 1.2.0) is a standalone software application intended for use by healthcare professionals during left atrial appendage closure (LAAC) procedures. It processes transesophageal echocardiography (TEE) images to assist in pre-procedural planning and device sizing. The software provides advanced image processing capabilities, including:

- 3D reconstruction of the left atrial appendage (LAA) from 2D TEE images.
- Visualization tools for reviewing 2D and 3D anatomical structures.
- Automated quantitative measurements of LAA dimensions and landing zone parameters.

WatchMate operates on a dedicated Hardware Platform and interfaces with a Mobile Platform for user interaction. It receives TEE image data from an ultrasound console via DICOM protocol and outputs 3D models and measurements to support clinical decision-making. The software does not directly interact with the patient and is intended for use in cardiac catheterization or electrophysiology labs by trained clinicians. It functions as an adjunctive tool, providing anatomical insights without replacing clinical judgment.

AI/ML Algorithm Development and Training:

WatchMate Software employs a multi-stage deep learning pipeline comprising: (1) video validation models that classify 2D B-Mode TEE input and confirm the presence of the LAA; (2) character recognition models that extract transducer angle and imaging depth metadata from each frame; (3) an anatomy segmentation model that identifies the LAA, Left Atrium, Left Pulmonary Vein, cardiac vessels, and Left Ventricle in each TEE frame; (4) 3D mesh generation models that construct a densified 3D point cloud from segmentation contours and convert it into a smooth surface mesh of the LAA and surrounding structures; and (5) a landing zone estimation algorithm that provides a tentative landing zone plane with quantitative measurements.

All models were developed using a de-identified clinical dataset sourced from a large United States health system spanning over 35 years of echocardiographic and cardiac CT imaging data. Training and verification data were split at the patient level to prevent data leakage. TEE-based models were trained on annotated TEE video frames; 3D reconstruction models were trained on 3D anatomical references derived from cardiac CT scans. The table below summarizes the datasets used for internal model development and verification.

Model	Training Dataset	Verification Dataset
Anatomy Segmentation	36,541 annotated TEE frames	7,385 annotated TEE frames
3D Point Cloud Generation	61,284 cardiac CT scans	3,270 cardiac CT scans

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The verification datasets were used for internal model tuning and selection and are distinct from the independent external clinical validation study (NCT07126600) described in the Clinical Testing Summary.

INDICATIONS FOR USE [807.92(A)(5)]

WatchMate Software enables visualization and measurement of structures of the heart and vessels for pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure.

To facilitate the above, WatchMate Software provides general functionality such as:

- 3D reconstruction of the left atrial appendage (LAA) from trans-esophageal echocardiogram images of the left atrial appendage
- Visualization and image reconstruction, including 2D review and 3D rendering
- Measurement and annotation tools

The results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment.

WatchMate Software's intended patient population is comprised of adult patients.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(A)(6)]

Table 1 summarizes a comparative analysis between WatchMate and the predicate and reference Devices. The information presented demonstrates that the proposed device is substantially equivalent to the predicate device.

510(k) Summary

Table 1: Summary of Technological Characteristics

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
Regulation Number, Regulation Name, Regulatory Class	21 CFR 892.2050 – Medical image management and processing system; Class II	21 CFR 892.2050 – Medical image management and processing system; Class II	21 CFR 892.2050 – Medical image management and processing system; Class II	21 CFR 892.2050 – Medical image management and processing system; Class II	Same.
Product Code, Device Classification Name	Primary Product Code: QIH	Primary Product Code: QIH, Secondary Product Code: LLZ; Medical image management and processing system	LLZ; Common Name - Picture Archiving and Communications System (PACS)	LLZ; Medical Image Management and Processing System	Same as predicate device.
Indications for Use	WatchMate Software enables visualization and measurement of structures of the heart and vessels for pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure. To facilitate the above, WatchMate Software provides general functionality such as: • 3D reconstruction of the left atrial appendage (LAA) from trans-esophageal echocardiogram images of the left atrial appendage • Visualization and image reconstruction, including 2D review and 3D rendering	TruPlan enables visualization and measurement of structures of the heart and vessels for: • Pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure • Post-procedural evaluation for the LAAC procedure To facilitate the above, TruPlan provides general functionality such as: • Segmentation of cardiovascular structures • Visualization and image reconstruction techniques: 2D	The 3D Auto LAA is a software application designed to view and quantify 3D image data acquired by Philips Ultrasound Systems for use in measuring the area, circumference, and diameter of a Left Atrial Appendage (LAA) orifice.	Fibroid Mapping Reviewer Application (FMRA) is intended to be used by physicians in the clinic or hospital to generate a 3-D model from ultrasound images of the uterus of women with uterine fibroids. The model represents clinically relevant dimensions, including the location and dimensions of the fibroid (maximum length, width and depth).	The proposed and predicate devices have the same general fundamental purpose: adjunctive, clinician directed Left Atrial Appendage Closure (LAAC) planning; differences are modality/scope which do not raise new/different questions of safety and effectiveness.

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Table 1: Summary of Technological Characteristics (cont.)

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
	• Measurement and annotation tools The results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment. WatchMate Software's intended patient population is comprised of adult patients.	review, Volume Rendering, MPR • Simulation of TEE views, ICE views, and fluoroscopic rendering • Measurement and annotation tools • Reporting tools TruPlan's intended patient population is comprised of adult patients.			
Intended Use Population	Adults undergoing LAAC	Adults undergoing LAAC	The Philips EPIQ and Affiniti Diagnostic Ultrasound Systems are for cardiac (adult, pediatric, and fetal)	Women with uterine fibroids	Same as predicate device.
Intended Use Environment	Control room or designated non-sterile area in hospital cardiac catheterization lab / cardiac electrophysiology lab	Clinical / Hospital environment	The Philips EPIQ and Affiniti Diagnostic Ultrasound Systems are intended for use in a variety of clinical environments, including hospitals, clinics, and point-of-care settings	Clinic/Hospital	All are professional clinical environments; differences do not change risk profile.
Intended User	Qualified HCPs (interventional cardiologists, electrophysiologists, sonographers)	Qualified medical professionals (cardiologists, electrophysiologists, radiologists)	Trained healthcare professional	Physicians	All require trained users; clinician oversight mitigates automation risks.

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Table 1: Summary of Technological Characteristics (cont.)

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
Prescription/Over the Counter	Rx-only	Rx-only	Rx-only	Rx-only	Same
System Components	Hardware Platform (Linux + NVIDIA GPU), Mobile Platform (iPad), Optional display; Helper Utilities (DICOM, Network, Auth, LUKS, Export/Archival, ROI, Device Placement, Device Simulation)	cvi42 client/server, Web viewer, Node42 (server-side ML), PACS connectivity	On-cart Philips EPIQ/Affiniti with 3D Auto LAA app	Windows software; imports ultrasound via USB	All are software-centric; platform differences are architectural and do not affect safety/effectiveness.
Operational Workflow / Clinical Workflow	• Acquire TEE sweep • select videos • 3D reconstruction • landing zone review • optional device simulation	• Import CT • segmentation/visualization • simulated views • measurement/reporting • follow-up module	• Acquire 3D TEE • semi-auto LAA orifice border • measure orifice parameters	• Import Ultrasound (US) frames • Annotate • 3D uterus model • measure fibroids	Comparable stepwise adjunct workflows: modality choice changes acquisition only.
Operating Principal / Principle of Operation	• TEE recognition (ML) • 3D reconstruction (ML) • landing-zone estimation (algorithmic); clinician review required	CT-based segmentation/visualization; ML used for segmentation and landing zone initialization; clinician review	Semi-automated LAA orifice border detection with user edits	Post-processing of 2D US to generate 3D model with manual annotations	All rely on user oversight; automation levels differ but do not introduce new risks.
Input data type	Up to three TEE DICOM videos with ECG gating, transducer angle, spatial resolution. Validated for compatibility with GE and Philips TEE ultrasound systems only.	CT data in DICOM format (vendor-independent)	3D TEE from Philips systems	Ultrasound; supports non-DICOM video (.mov/.avi/.mp4)	Different modalities feed comparable planning functions.
Landing Zone Detection	AI-estimated plane; user-adjustable; live measurement updates	Semi-automatic initialization of the landing zone using Machine Learning	Semi-automated orifice border (LAA) with editable contour	Not Applicable	All require clinician control; no new safety concerns.

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Table 1: Summary of Technological Characteristics (cont.)

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
		techniques; manual confirmation of the landing zone			
Left Heart Segmentation	AI recognition; 3D LAA/LA/LPV/ mitral annulus/vessels; echo & structure overlays	Semi-automatic segmentation for 3D visualization of the left heart using Machine Learning techniques; manual editing of 3D views possible	Focused on LAA orifice only	Uterus/fibroid segmentation	Scope difference only; no safety impact.
Study list image functionality	TEE Video Viewer (list/grid and play/pause), qualified videos, QC feedback	• Study/series previewing • Exporting • Deleting • Anonymizing • Search	On-cart workflow; Not applicable for generic study list	Local/USB import; Not Applicable for full study list features	Differences are workflow related; not safety relevant.
Image assessment – simulated views	Echo overlay (TEE pane overlay on top of the 3D Model) and Structure Overlay (ECG-Gated TEE frames)	• Fluoroscopy (grayscale 3D rendering), to visualize relationship among LAAC procedure relevant anatomical structures • TEE, to provide similar views to intraprocedural TEE • ICE, to provide similar views to intraprocedural ICE	--	Not Applicable	Different visualization aids; no new risks.
Image assessment – other visualization functionality	Two-pane 2D TEE plus 3D, clip plane, rotate/pan/zoom, structure overlays	2D/3D/MPR, 4D (cine), MPR, MIP, Annotation	MPR alignment; editable orifice border visualization	2D review plus 3D uterus rendering	Feature breadth varies; all adequate for planning.
Image assessment – measurement functionality	Max/Min diameters, area/perimeter-based	Distance (length, diameter, perimeter)/	Area, circumference, max/min diameters	Length/width/depth (fibroids); location mapping	All provide clinically relevant measurements; modality specific.

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Table 1: Summary of Technological Characteristics (cont.)

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
	diameters, depth, compression ratios	Area / Angle/ Signal intensity / Coordinates			
Report functionality	Export & Archival Service (USB/DICOM); encrypted logs	Patient/study information; Screenshots; Measurements; Free text; Device sizing table (for reference only) for LAA procedure	Outputs for clinician review; Not Applicable for formal reporting	Outputs for clinician review; Not Applicable for formal reporting	Differences are presentational; not safety critical.
Operating system	Ubuntu 24.04 LTS + iPad UI; optional HDMI connection to cath lab monitor	Windows/macOS clients; cvi42 server; web components	On-cart EPIQ/Affiniti	Windows workstation	OS/platform differences are architectural; do not affect clinical performance.
DICOM compliant	Yes (DICOM service, AE/whitelist; mTLS; local-only network)	Yes (SCP/Q/R/TLS; PACS integration)	Yes, within Philips ecosystem	Mixed: supports non-DICOM video; US import via USB	All support clinical data workflows: format differences are expected.
Use of AI/Machine Learning	Yes: TEE recognition, 3D reconstruction; landing zone estimation	Yes: left heart segmentation; landing zone initialization	Preliminary border generated by algorithm	No (manual annotations; algorithmic post-processing)	Automation levels vary; all retain clinician oversight.
Interoperability / Connectivity	Local private network; DICOM from TEE console via Ethernet/Wi-Fi; iPad via Wi-Fi; HDMI display	PACS Q/R, DICOM SCP, TLS; AD/LDAP; web ports	On-cart workflow; Not Applicable beyond Philips ecosystem	USB import; Not Applicable for networked interoperability	Interoperability differences reflect deployment model; not safety critical.
Software / Hardware Platform	Linux workstation (GPU ≥24 GB RAM), iPad mobile client, optional HDMI display	Windows/macOS clients; Windows server; Node42 for ML	Philips ultrasound cart (EPIQ/Affiniti)	Windows PC	Platform differences are architectural.
Automatic Updates & Cybersecurity	Updates via secure links; 2FA; Tripwire FIM; cert renewal; LUKS FDE; mTLS; local-only network	TLS for web/PACS; admin/user roles; antivirus guidance; AD/LDAP; HTTPS/TLS	--	--	Both proposed and predicate implement robust cybersecurity; differences are implementation specific.
Non-Clinical Testing	Non-clinical performance testing for WatchMate was	Performance testing for TruPlan was conducted	Non-clinical testing for the Philips 3D Auto LAA	FMRA underwent comprehensive	Both the proposed WatchMate Software

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Table 1: Summary of Technological Characteristics (cont.)

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
	conducted in compliance with ISO 13485, IEC 62304 software lifecycle and ISO 14971 risk management frameworks and includes a documented cybersecurity risk assessment. Non-clinical performance testing demonstrated that WatchMate Software meets all design input requirements and performs reliably as intended. Testing included software unit, system, and integration verification; product cybersecurity evaluation; and labeling verification, all conducted under predefined protocols, acceptance criteria, and approved procedures. Unit and system testing confirmed correct functionality of individual components and the fully integrated software, while cybersecurity testing verified resilience in both controlled and mock deployment environments. Labeling verification ensured accuracy and completeness of all	in compliance with ISO 13485:2016, IEC 62304:2015, ISO 14971:2019, and NEMA 3.1-3.20 (2016) DICOM standards to verify design requirements and ensure device functionality. Testing included verification, validation, and machine learning algorithm evaluation for left heart segmentation and landing zone detection using anonymized CT images from multiple vendors and global sites. Results met predefined acceptance criteria, achieving 99.81% bone removal and 97.37% correct LAA visualization for segmentation, and 97–99% accuracy for landing zone detection with minimal mean distance errors, confirming robust performance across diverse datasets.	cardiac quantification application was performed following Philips' internal processes, including design control activities such as requirements review, risk analysis, product specifications, and software verification and validation. Verification and validation testing, along with a performance validation study, demonstrated that the new automated LAA application (part of EPIQ/Affiniti System software version 7.0) was substantially equivalent to the currently marketed manual LAA tracing and measurement options, ensuring safe and effective performance.	verification and validation, including comparison of its output parameters against MRI values using phantom models simulating uterus and fibroids, with acceptance criteria of ±2 mm for location and dimensions. Testing was performed by three certified medical professionals using images from three different ultrasound machines. Development adhered to ISO 14971:2019 and IEC 62304:2015 standards. FMRA met all acceptance criteria, confirming compliance with performance, functional, and safety requirements, and demonstrated substantial equivalence to the predicate device without raising new safety or effectiveness concerns.	and the predicate TruPlan device underwent comprehensive non-clinical verification and validation activities appropriate to their respective designs, user needs, and intended uses. For WatchMate, software verification, integration testing, and cybersecurity evaluations demonstrated that the system performs reliably and meets all specified requirements. Similarly, the predicate TruPlan device completed non-clinical testing, including segmentation and algorithm performance assessments, that confirmed acceptable functionality and accuracy using CT image datasets. The non-clinical testing for both devices confirms that each performs as intended within its defined operating parameters and do not introduce any new risks.

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Table 1: Summary of Technological Characteristics (cont.)

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
	user-facing documentation. All tests passed successfully, with all acceptance criteria met.				
Clinical Testing	No clinical studies were necessary to support substantial equivalence. No clinical testing was necessary, however a prospective multicenter data collection study (NCT07126600) was elected to be performed. All imaging was collected as part of routine standard-of-care clinical practice, and no investigational procedures were performed. This study evaluated WatchMate's performance for LAAC planning by comparing its LAA measurements from routine intraprocedural 2D TEE with unanimous-consensus contrast-enhanced CT as the reference standard established by three independent expert cardiac CT readers. 100 subjects were enrolled	No clinical studies were necessary to support substantial equivalence	Did not require clinical data in order to make a determination for substantial equivalence	--	Although the predicate device did not conduct a formal prospective clinical study, both the predicate and the proposed device were evaluated using methodologies that compare software generated measurements to human reviewer assessments with CT serving as the gold standard. The predicate's CT based performance assessments were classified under its non-clinical testing, whereas the proposed device conducted a prospective multicenter data collection study. Despite different study designs, each device demonstrated that its measurement performance is consistent with that of

510(k) Summary

Table 1: Summary of Technological Characteristics (cont.)

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
	across six U.S. sites, with 72 included in the per-protocol population after exclusions for unanalyzable TEE or 2D–3D inconsistency flags. The primary endpoint demonstrated non-inferiority of WatchMate to the average of three blinded physician-interpreted 2D TEE for landing-zone maximum diameter, with mean absolute deviation vs. consensus CT of 3.1 ± 3.4 mm for WatchMate and 5.2 ± 3.4 mm for 2D TEE, and a between-method difference of –2.1 mm (upper 97.5% CI -0.9 mm; P < 0.001), meeting the prespecified 1-mm non-inferiority margin and additionally meeting superiority. Sensitivity analyses against each individual CT reader and against each individual TEE reader as alternative reference standards consistently demonstrated non-inferiority. Secondary analyses (e.g., landing-zone depth and				qualified human reviewers and aligned with CT reference measurements, WatchMate Software showed non-inferiority to physician interpreted 2D TEE for key LAA measurements relative to CT. In both cases, performance testing confirmed that the software outputs agree with human reviewer measurements without introducing new risks or affecting safety or effectiveness.

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Table 1: Summary of Technological Characteristics (cont.)

Feature	Proposed Device WatchMate Software	Predicate Device: TruPlan CT Imaging Software (K222593)	Reference Device 1: 3D Auto LAA (K201352)	Reference Device 2: FMRA (K222683)	Rationale for Substantial Equivalence
	minimum diameter) showed comparable performance to TEE, and Bland–Altman analysis indicated minimal systematic bias for WatchMate versus consistent TEE underestimation. Overall, the study demonstrated that WatchMate is non-inferior to physician-interpreted 2D TEE for LAA landing-zone diameter measurement relative to multi-reader consensus CT, supporting its clinical use in LAAC pre-procedural planning.				

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SUBSTANTIAL EQUIVALENCE

The WatchMate Software and the predicate device, TruPlan CT Imaging Software (K222593), both are prescription-use systems intended for adult patients undergoing left atrial appendage closure (LAAC) procedures. Like the predicate, WatchMate provides 3D visualization, measurement, and annotation tools to support pre-procedural planning; however, it differs primarily in its use of TEE-based input data rather than CT, and in its machine-learning-driven workflows for TEE view recognition, 3D reconstruction, and landing-zone estimation. Both systems employ AI/ML for segmentation or initialization tasks with required clinician confirmation, offer comparable 2D/3D visualization and measurement capabilities, and are DICOM-compliant. WatchMate's hardware/software environment (Linux-based GPU workstation with iPad client) differs from TruPlan's Windows/macOS client-server architecture yet both incorporate secure data handling and cybersecurity controls. Non-clinical testing demonstrated that WatchMate meets all design, performance, and cybersecurity requirements, and a prospective multicenter clinical study confirmed its non-inferior performance to the average of three blinded physician-interpreted 2D TEE readers against a unanimous-consensus three-reader CT reference standard, for LAAC landing-zone measurement. Overall, the differences in input modality, workflow, and platform do not raise new questions of safety or effectiveness.

PERFORMANCE DATA [807.92(B)]

[807.92(B)(1)] NONCLINICAL TESTING SUMMARY:

Anumana has completed comprehensive design verification and validation testing, including software verification & validation (Unit/Integration/System); cybersecurity testing (product security) and labeling verification testing to ensure that the proposed WatchMate met its intended use and to confirm that differences between the subject and predicate device do not raise new and different questions of safety and effectiveness. WatchMate also provided clinical validation testing.

All necessary performance testing was conducted on WatchMate with passing results supporting the determination of substantial equivalence to the predicate device. Please refer to *Verification and Validation Testing* attachment of eSTAR section *Software/Firmware, Cybersecurity, and Interoperability*. The testing included following:

1. **Software Verification Testing**
    a. **Software Unit Testing**
    Unit testing was performed on the individual software components. Tests verified component-level functionality, including the AI/ML pipeline, APIs, and frontend components. All unit tests passed, and no design or code changes were required beyond documentation updates.
    b. **System and Integration Testing**
    System testing evaluated the fully integrated software system using a production-equivalent build. Testing confirmed compliance with functional, usability, compatibility, data-management, DICOM-conformance, error-handling, and quality requirements.

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2. **Cybersecurity Testing**

Cybersecurity verification included evaluation of the product's resilience to cybersecurity threats. A Mock Environment Cybersecurity Test was also conducted to confirm secure performance within a simulated intended-use deployment environment. Testing assessed API security, secure data storage, and system behavior under potential threat conditions. All cybersecurity controls met acceptance criteria.

3. **Labeling Verification**

Labeling verification confirmed that labeling content—including the Instructions for Use and Installation Manual—is accurate, complete, and compliant with applicable requirements. All labeling requirements were verified using the Labeling Verification Datasheet and Report, and all acceptance criteria were met.

[807.92(B)(2)] CLINICAL TESTING SUMMARY:

A prospective, multi-center clinical data collection study (NCT07126600) was conducted to evaluate the performance of the Anumana's WatchMate Software in patients undergoing left atrial appendage closure (LAAC). The study was designed to validate WatchMate measurements of left atrial appendage (LAA) anatomy using intra-procedural 2D transesophageal echocardiography (TEE) as input and contrast-enhanced computed tomography (CT) as the reference standard. All imaging was collected as part of routine standard-of-care clinical practice, and no investigational procedures were performed.

The CT reference standard was established using three independent expert cardiac CT readers. Each reader independently measured LAA parameters while blinded to the other readers' measurements, the TEE images and WatchMate outputs. A structured unanimous-consensus methodology was applied. The 2D TEE comparator was established using the average of all three blinded TEE readers performing measurements in accordance with the WATCHMAN Instructions for Use.

A total of 100 subjects were enrolled across 6 U.S. centers, with 72 subjects included in the per-protocol (PP) population. Exclusions occurred due to unanalyzable TEE data or WatchMate 2D–3D inconsistency check.

The primary endpoint evaluated non-inferiority of WatchMate to the average of three physician-interpreted 2D TEE readers in quantifying the LAA landing zone maximum diameter, with the consensus CT serving as the ground truth. Non-inferiority was achieved as shown below:

- Mean absolute deviation vs. CT: WatchMate 3.1 ± 3.4 mm, Physician-interpreted 2D TEE (average of three readers) 5.2 ± 3.4 mm
- Difference (WatchMate – TEE): –2.1 mm, upper 97.5% CI -0.9 mm, meeting the pre-specified non-inferiority margin of 1 mm ($P < 0.001$)

The upper bound of the 97.5% confidence interval was less than zero, so superiority of WatchMate over the average of three 2D TEE readers was also demonstrated.

The primary endpoint was re-computed using each individual CT reader as the reference standard (with the 2D TEE comparator held fixed as the average of three TEE readers); non-inferiority was met under each of the three alternative CT reference standards. The endpoint was also re-

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computed using each individual TEE reader as the comparator against the consensus CT reference standard; non-inferiority was met for each of the three TEE readers ($P < 0.001$ in all three analyses).

Additional descriptive endpoints (landing zone maximum depth and landing zone minimum diameter) demonstrated WatchMate performance comparable to physician-interpreted 2D TEE relative to CT. Bland–Altman analyses showed minimal systematic bias for WatchMate in landing zone maximum diameter, whereas 2D TEE demonstrated consistent underestimation.

Subgroup analyses (sex, age, race, ethnicity, LAA morphology) showed no significant interactions, indicating consistent performance across clinically relevant sub-groups.

Overall, clinical testing demonstrated that the Anumana WatchMate Software is non-inferior to the average of three physician-interpreted 2D TEE readers for quantifying LAA landing zone maximum diameter when compared with a multi-reader consensus CT reference standard, supporting its use for visualization and measurement of cardiac structures during LAAC planning.

CONCLUSIONS [807.92(B)(3)]

The proposed WatchMate is substantially equivalent to the predicate device, TruPlan (K222593). Both devices have the same general fundamental purpose: “adjunctive, clinician directed Left Atrial Appendage Closure (LAAC) planning.” Anumana has performed comprehensive verification and validation activities to demonstrate that the WatchMate meets all required specifications. The testing demonstrates that the technological differences between the proposed predicate and references devices do not raise different questions of safety or effectiveness.