



May 22, 2026

Canon Medical Informatics, Inc.
Jay Vaishnav
Director, Regulatory Affairs
5850 Opus Parkway, Suite 300
Minnetonka, Minnesota 55343

Re: K260324

Trade/Device Name: Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: April 23, 2026
Received: April 23, 2026

Dear Jay Vaishnav:

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,

A handwritten signature in black ink, appearing to read "Samuel", followed by a stylized flourish. A large, light blue "FDA" watermark is visible in the background.

for

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
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.

K260324

?

Please provide the device trade name(s).

?

Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning

Please provide your Indications for Use below.

?

Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning is a non-invasive post-processing application designed to assist medical professionals with the assessment of the aortic valve and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures. Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning includes general functionality such as:

- The software processes CT (computed tomography) image data to provide 3D segmentation of heart structures and vessels relevant to approach planning.
- The user can review the 2D and 3D images to select and plan the delivery path.
- The user can determine C-arm angles for use during the procedure.
- The user can verify and adjust the results of segmentation and cross-section measurements.
- The software provides visualization techniques such as volume rendering, MIP, MPR and curved MPR.
- The user can identify and edit contours and the centerline automatically or manually.
- The user can generate a report with relevant approach planning data and measurements for device sizing.
- The software can provide visualization of calcium.
- The user can generate tortuosity calculations along a centerline.

The TAVR Planning Assist feature offers the ability to automatically initialize visualizations and measurements, that users can edit. The calculation of these outputs utilizes artificial intelligence/machine learning methods.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary - Vitrea CT TAVR Planning

I. Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Canon Medical Informatics, Inc.
Applicant Address	5850 Opus Parkway, Suite 300 Minnetonka MN 55343 United States of America
Applicant and Correspondent	Jay Vaishnav, PhD, RAC, FRAPS Director, Regulatory Affairs Phone 952-487-9530 E-mail Jay.Vaishnav@mi.medical.canon
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II. Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning
Common Name	TAVR Planning
Classification Name	Medical image management and processing system
Regulation Number	21 CFR 892.2050
Product Code(s)	Product Code: QIH

III. Predicate Device

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name	Product Code
K122578	Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning	LLZ

IV. Device Description Summary

21 CFR 807.92(a)(4)

How the Device Functions

The Vitrea CT Transcatheter Aortic Valve Replacement (TAVR) Planning software is a non-invasive post-processing application designed to assist medical professionals with the assessment of the aortic valve and in pre-operational planning and post-operative evaluation of TAVR procedures. The software processes CT (computed tomography) image data to provide 3D segmentation of heart structures and vessels relevant to approach planning. It allows users to review 2D and 3D images to select and plan the delivery path, determine C-arm angles for use during the procedure, verify and adjust the results of segmentation and cross-section measurements, and generate reports with relevant approach planning data and measurements for device sizing.

Scientific Concepts That Form the Basis of the Device

The TAVR Planning Assist feature¹ incorporates AI/ML methods for segmentation and landmark detection to establish the valve plane. The software uses deep learning algorithms for identifying anatomical landmarks. The segmentation module generates preliminary measurement results from the segmentations and landmarks. The device provides initial values of the aortic root measurements based on segmentation and landmarks, which the user can edit and review before finalizing a report.

Proposed Conditions for Use

The Vitrea CT TAVR Planning software is intended for use on patients who have been identified as candidates for TAVR procedures. The software enables assessment and measurement of the aortic valve and related ventricles, providing techniques to assess the feasibility of a trans-apical, iliac (transfemoral), or subclavian approach to structures for replacement or repair procedures. The device is for use in a clinical setting and is intended for qualified users such as cardiologists, radiologists, and clinical specialists.

Physical and Performance Characteristics of the Device

Physical Characteristics

The device is Software as a Medical Device (SaMD) and has no hardware or material components.

Performance Characteristics

Bench testing on 89 retrospective CT cases demonstrated that the device performs with high accuracy and strong agreement relative to expert manual measurements, as measured by intraclass correlation coefficients.² Bland-Altman analyses showed low measurement bias and variability comparable to human inter-reader performance. The device showed consistent performance across all subgroups—scanner type, slice thickness, kVp, calcification severity, demographics, and reconstruction kernels, and the leaflet visualization feature surpassed acceptance criteria with over 93% of cases rated “Good” or “Excellent” by

¹Canon Medical Informatics may market the TAVR Planning Assist feature as TAVR Assist+.

² LVOT measurement was validated at the default setting of 3 mm from the valve plane

expert readers. Overall, the software demonstrated robust, reliable, and clinically acceptable performance without introducing new safety or effectiveness concerns.

How the Device Interacts with Other Devices and the Patient

The device is a software application that resides on the Vitrea platform (K172855). The device does not interact directly with patients; it performs postprocessing operations on CTA DICOM patient images. Results can be exported to image management, archival, or reporting systems that support DICOM standards for further review and interpretation. Results can also be saved in DICOM Structured Report (DICOM SR) format.

V. Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Vitreia CT Transcatheter Aortic Valve Replacement (TAVR) Planning is a non-invasive post-processing application designed to assist medical professionals with the assessment of the aortic valve and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures. Vitreia CT Transcatheter Aortic Valve Replacement (TAVR) Planning includes general functionality such as:

- The software processes CT (computed tomography) image data to provide 3D segmentation of heart structures and vessels relevant to approach planning.
- The user can review the 2D and 3D images to select and plan the delivery path.
- The user can determine C-arm angles for use during the procedure.
- The user can verify and adjust the results of segmentation and cross-section measurements.
- The software provides visualization techniques such as volume rendering, MIP, MPR and curved MPR.
- The user can identify and edit contours and the centerline automatically or manually. The user can generate a report with relevant approach planning data and measurements for device sizing.
- The software can provide visualization of calcium.
- The user can generate tortuosity calculations along a centerline.

The TAVR Planning Assist feature offers the ability to automatically initialize visualizations and measurements, that users can edit. The calculation of these outputs utilizes artificial intelligence/machine learning methods.

VI. Indications for Use Comparison

21 CFR 807.92(a)(5)

The following text has been added to the IFU, as compared to the predicate:

“The TAVR Planning Assist feature offers the ability to automatically initialize visualizations and measurements, that users can edit. The calculation of these outputs utilizes artificial intelligence/machine learning methods.”

The additional text reflects the addition of automatic initialization of device outputs, that does not change the Intended Use of the subject device from the predicate device. Users retain the ability to edit any automatically initialized results, and performance testing demonstrates that the automatically initialized measurements maintain agreement with expert ground-truth and predicate measurements.

VII. Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate devices are intended for use with CTA DICOM images to support TAVR planning by measuring aortic root anatomy and vascular access dimensions. The subject device uses deep learning methods to perform some of the segmentation and landmark identification required to initialize measurements, whereas the predicate device uses traditional segmentation and pattern identification algorithms and automatically initializes fewer outputs. The reference device automates some of the measurements using AI/ML. All automatically initialized outputs from the subject device are user reviewable and editable. All algorithms and functionality associated with this feature are imported unchanged from Canon's previously cleared Endovascular Stent Planning Software (cleared as K091498, updated K143079). Regression testing was conducted to validate that the functionality integrated correctly with the rest of the device.

Table 1 summarizes the key feature/technological differences and similarities between the predicate device and the proposed device:

Table 1: Substantial Equivalence Comparison

Characteristic	Subject Device Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: QIH	Predicate Device (K122578) Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: LLZ	Analysis of Similarities and Differences
Intended Use	Allows users to make measurements that assist qualified medical professionals in either planning TAVR procedures or in evaluating results post-operatively.	Same	Same
Indications for Use	Vitre CT Transcatheter Aortic Valve Replacement (TAVR) Planning is a non-invasive post-processing application designed to assist medical professionals with the assessment of the aortic valve and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures. Vitre CT Transcatheter Aortic Valve Replacement (TAVR) Planning includes general functionality such as • The software processes CT (computed tomography) image data to provide 3D segmentation of heart structures and vessels relevant to approach planning. • The user can review the 2D and 3D images to select and plan the delivery path. • The user can determine C-arm angles for use during the procedure. • The user can verify and adjust the results of segmentation and cross-section measurements.	Vitre CT Transcatheter Aortic Valve Replacement (TAVR) Planning is a non-invasive post-processing application designed to assist medical professionals with the assessment of the aortic valve and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures. Vitre CT Transcatheter Aortic Valve Replacement (TAVR) Planning includes general functionality such as • The software processes CT (computed tomography) image data to provide 3D segmentation of heart structures and vessels relevant to approach planning. • The user can review the 2D and 3D images to select and plan the delivery path. • The user can determine C-arm angles for use during the procedure. • The user can verify and adjust the results of segmentation and cross-section measurements.	The following text has been added to the IFU: <i>“The TAVR Planning Assist feature offers the ability to automatically initialize visualizations and measurements, that users can edit. The calculation of these outputs utilizes artificial intelligence/machine learning methods.”</i> The additional text reflects the addition of automatic initialization of device outputs, that does not change the Intended Use of the subject device from the predicate device. Users retain the ability to edit any automatically initialized results, and performance testing demonstrates that the

Characteristic	Subject Device Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: QIH	Predicate Device (K122578) Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: LLZ	Analysis of Similarities and Differences
	- The software provides visualization techniques such as volume rendering, MIP, MPR and curved MPR. - The user can identify and edit contours and the centerline automatically or manually. The user can generate a report with relevant approach planning data and measurements for device sizing. - The software can provide visualization of calcium. - The user can generate tortuosity calculations along a centerline. The TAVR Planning Assist feature offers the ability to automatically initialize visualizations and measurements, that users can edit. The calculation of these outputs utilizes artificial intelligence/machine learning methods.	- The software provides visualization techniques such as volume rendering, MIP, MPR and curved MPR. - The user can identify and edit contours and the centerline automatically or manually. The user can generate a report with relevant approach planning data and measurements for device sizing. - The software can provide visualization of calcium. - The user can generate tortuosity calculations along a centerline.	automatically initialized measurements maintain agreement with expert ground-truth and predicate measurements.
Target Population	Patients indicated for a TAVR procedure	Same	Same
Intended Users	Cardiologists, radiologists and clinical specialists	Same	Same
Anatomical Sites	Aortic valve and ventricles	Same	Same
Use Environment	Clinical environment	Same	Same

Characteristic	Subject Device Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: QIH	Predicate Device (K122578) Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: LLZ	Analysis of Similarities and Differences
Human Factors	The software is designed for use on a radiology workstation	Same	Same
Use of Contrast	The software requires contrast enhanced CTA images	Same	Same
DICOM Standard Compliance	The software processes DICOM-compliant CT image data	Same	Same
Image Display and Visualization			
Provides an option to display vascular anatomy in stretched MPR, orthogonal, multi-dimensional, curved MPR, oblique, MIP, MinIP, and 3D views.	Yes	Yes	Same
Allows visualization of calcium	Yes	Yes	Same
Image Processing, including Segmentation and Measurement			
Measurements of aortic structures	The software uses AI/ML algorithms to automatically initialize the following measurements (the user can edit the initialized value): - Aortic annulus contour measurements (area, perimeter, min/max/effective diameters) - Annulus to Left Main coronary artery (LM) height. - Annulus to Right Coronary Artery (RCA) height. - Aortic root coronal angle.	Users can manually make the following measurements: - Aortic annulus contour measurements (area, perimeter, min/max/effective diameters) - Annulus to Left Main coronary artery (LM) height - Annulus to Right Coronary Artery (RCA) height - Aortic root coronal angle - Left ventricular outflow tract (LVOT) contour measurements (area, perimeter, min/max/effective diameters)	The subject device initializes some of the measurements that a user had to make manually in the predicate. The initialization uses locked AI/ML algorithms in segmentation and landmark detection. The predicate device allowed the user to make and label any measurement, but the subject device explicitly adds the max

Characteristic	Subject Device Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: QIH	Predicate Device (K122578) Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: LLZ	Analysis of Similarities and Differences
	- Left ventricular outflow tract (LVOT) contour measurements (area, perimeter, min/max/effective diameters). - The sinus of Valsalva cusp to commissure distance measurements Users can manually make the following measurements: - Sinotubular junction (STJ) contour measurements (area, perimeter, min/max/effective diameters) - Sinotubular Junction (STJ) height - Sinus of Valsalva contour measurements (area, perimeter, min/max/effective diameters) - Sinus of Valsalva height - Max ascending aorta contour measurements (area, perimeter, min/max/effective diameters) Users can also make any other manual measurement they choose, and label it appropriately.	- Sinotubular junction (STJ) contour measurements (area, perimeter, min/max/effective diameters) - Sinotubular Junction (STJ) height - Sinus of Valsalva contour measurements (area, perimeter, min/max/effective diameters) - Sinus of Valsalva height - Sinus of Valsalva cusp to commissure distances Users can also make any other manual measurement they choose, and label it appropriately.	ascending aorta contour measurements to the list of available manual measurements. The user has the ability to edit all initialized outputs and must manually approve all output before reporting.
Vascular access measurements	Algorithms and functionality associated with vascular access features have been replaced with the version from Canon's previously cleared Endovascular Stent Planning Software (cleared as K091498, updated K143079).	The software initializes the following measurements (the user can edit the initialized value, and AI/ML is not used in the initialization): Left & right iliac maximum tortuosity Users can manually make the following measurements:	The predicate device initialized one vascular access measurement. The subject device replaces the vascular access algorithm with the version from Canon's previously cleared Endovascular

Characteristic	Subject Device Vitrea CT TAVR Planning 21 CFR 892.2050 Product Code: QIH	Predicate Device (K122578) Vitrea CT TAVR Planning 21 CFR 892.2050 Product Code: LLZ	Analysis of Similarities and Differences
	The software initializes the following measurements (the user can edit the initialized value): - Left & right iliac maximum tortuosity - Left & right femoral iliac minimum diameter - Left & right external iliac minimum diameter - Left & right common iliac minimum diameter - Minimum abdominal aorta diameter The initialization does not use AI/ML.	- Left & right femoral iliac minimum diameter - Left & right external iliac minimum diameter - Left & right common iliac minimum diameter - Minimum abdominal aorta diameter	Stent Planning Software (cleared as K091498, updated K143079), that initializes all the vascular access measurements. For both devices, automatic initialization does not use AI/ML. For both devices, the user has the ability to edit, and is required to review, all initialized values. Integration testing was performed to ensure that the integration of previously cleared algorithms did not impact the safety and effectiveness of the device.
Segmentation and display of aortic structures	Semi-automated; adds segmentation of aortic leaflets for qualitative visualization purposes only	Semi-automated	Subject device adds visualization of leaflets. The visualization was evaluated by expert readers and does not impact the safety and effectiveness of the device as compared to the predicate.
Detection of annulus plane	Semi-automated	Same	Same
Detection of anatomical landmarks	Semi-automated detection of - right coronary cusp landmark, - left coronary cusp landmark, - non-coronary cusp landmark,	Manual identification of the same landmarks	The subject device uses AI/ML methods to automatically detect several landmarks that had to be identified manually in the

Characteristic	Subject Device Vitrea CT TAVR Planning 21 CFR 892.2050 Product Code: QIH	Predicate Device (K122578) Vitrea CT TAVR Planning 21 CFR 892.2050 Product Code: LLZ	Analysis of Similarities and Differences
	right coronary ostium and left coronary ostium.		predicate. The user can edit and must review any automatic output before reporting. Reference device K233209 also uses AI/ML methods for automatic TAVR planning functionality.
Detection of relevant vessel centerlines and calculation of diameter, area, and tortuosity	Semi-automated	Same	Same
Contour detection	Semi-automated contour detection with diameter, area, and distance measurements of annulus plane, as well as distance to each coronary ostia from the annulus plane	Same	Same
Use of AI/ML methods	Uses AI/ML for segmentation and landmark detection.	Does not use AI/ML	The predicate device does not use any AI/ML. The TAVR planning feature in Reference device K233209 uses AI/ML. The use of AI/ML in automatic initialization of device outputs does not change the Intended Use of the subject device from that of the predicate device.

Characteristic	Subject Device Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: QIH	Predicate Device (K122578) Vitre CT TAVR Planning 21 CFR 892.2050 Product Code: LLZ	Analysis of Similarities and Differences
			Users retain the ability to edit any automatically initialized results, and performance testing demonstrates that the automatically initialized measurements maintain agreement with expert ground-truth and predicate measurements.
Reporting			
The software provides tools to generate reports to distribute findings.	Yes	Yes	Same
DICOM SR	Yes	No	Users can export reports in a Structured Report format, if they have a license.

In summary, the main difference between the subject and predicate device is that the subject device adds AI/ML based automatic initialization of aortic root measurements, whereas the predicate device only allowed the user to make these measurements manually. These differences do not raise new questions of safety or effectiveness. The subject device's algorithms have been validated through performance testing, meeting pre-specified acceptance criteria and demonstrating accuracy and reliability.

The new functionality is similar to that in reference device K233209 (uOmnispace.CT, United Imaging), which also makes AI/ML enabled semi-automated measurements of the aortic root.

VIII. Non-Clinical and/or Clinical Tests, Summary and Conclusions

The device was trained and tuned using diverse retrospective CT data representing a wide range of patient anatomies, acquisition protocols, scanner manufacturers, and disease presentations relevant to TAVR planning. The training set consisted of 218 cases.

The validation dataset for the aortic root measurements included 89 independent TAVR CT planning cases spanning multiple U.S. and international institutions, with diversity in demographics (age, sex), imaging characteristics (scanner vendor, scanner model, slice thickness, kVp), and calcification severity. Scanner representation included Canon, GE, Philips, and Siemens systems).

Characteristics of the dataset follow:

Demographic distribution (Gender, Age, Ethnicity)

Gender

- Female: 30
- Male: 42
- Unknown: 17

Age

- 50–59 years: 2
- 60–69 years: 8
- 70–79 years: 15
- 80–89 years: 20
- 90–99 years: 5
- Unknown: 39

Ethnicity

Structured race and ethnicity data were not available in the anonymized dataset. Geographic and site diversity were used as a proxy for racial and ethnic diversity, based on U.S. Census data for the contributing regions. The sites used included a mix of academic, community, and federal hospitals spanning four major US geographic regions, as well as data from outside the US.

Clinical Subgroups and Confounders

The validation dataset was intentionally designed to include these clinical subgroups and confounders, with subgroup performance analyses performed:

- **Sex:** Male, Female, Unknown
- **Age:** 50–79 years, ≥80 years, Unknown
- **Valve Calcification Severity:** None (n=18), Mild/Moderate (n=35), Severe (n=36)

The validation dataset also includes challenging and edge cases related to anatomy and imaging conditions:

- LVOT calcification
- Horizontal aorta (high coronal angle)
- Reduced IV contrast
- Low kVp imaging (<120 kVp)

Exclusions

- Cases with severe motion artifacts
- Poor contrast or non-diagnostic phases

Equipment and Protocols for Image Acquisition

CT Equipment

- Scanners from Canon, Siemens, GE, and Philips were used.

Imaging Protocol Parameters

- Slice thickness: ≤1.0 mm (subgroups ≤0.5 mm, >0.5–1.0 mm).
- Tube energy: 100–120 kVp.
- Cardiac phases: systolic (20–30%) and diastolic (~80%).

Truthing Process

- Ground truth measurements were determined by two independent, board-certified cardiac CT readers.
- The FDA-cleared predicate device was used to manually generate these measurements.
- Each reader was unaware of the other's findings and did not see the automated results.
- For every measurement, the ground truth was established by averaging the values from both readers.
- Agreement between the readers was documented to ensure consistency with the TAVR literature previously published.

Validation truthers were completely independent of training truthers. The validation dataset was retrospective and distinct from any training activities. The device performance was measured by comparing device outputs with ground truth created manually by expert physicians. The overall device performance is summarized in Table 2.

Table 2: Measurement Accuracy (Retrospective validation; n=89)

Measurement	Intra-Class Correlation (ICC)	Acceptance criterion	95% CI	Bland-Altman Bias (%)
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Annulus area (mm ²)	0.95	>0.90	[0.92, 0.96]	-4.1%
Annulus perimeter (mm)	0.94	>0.90	[0.91, 0.96]	-2.5%
Derived diameter (mm)	0.95	>0.90	[0.92, 0.97]	-1.9%
Min diameter (mm)	0.91	>0.85	[0.87, 0.94]	-1.9%
Max diameter (mm)	0.93	>0.85	[0.90, 0.95]	-2.8%
LM coronary height (mm)	0.91	>0.80	[0.87, 0.94]	3.0%
RCA coronary height (mm)	0.94	>0.80	[0.91, 0.96]	-2.4%
Aortic root angle (°)	0.97	>0.90	[0.95, 0.98]	1.0%
LVOT area (mm ²)	0.92	>0.90	[0.89, 0.95]	-5.4%
LVOT perimeter (mm)	0.91	>0.90	[0.86, 0.94]	-3.0%
LVOT derived diameter (mm)	0.93	>0.90	[0.90, 0.95]	-2.4%
LVOT min diameter (mm)	0.92	>0.90	[0.87, 0.94]	-2.4%
LVOT max diameter (mm)	0.86	>0.90	[0.80, 0.91]	-3.6%
Sinus of Valsalva R (mm)	0.96	>0.90	[0.93, 0.97]	-1.0%
Sinus of Valsalva L (mm)	0.96	>0.90	[0.95, 0.98]	-1.0%
Sinus of Valsalva NC (mm)	0.97	>0.90	[0.95, 0.98]	0.1%

All primary measurements met their pre-specified acceptance criteria except for the LVOT maximum diameter, which demonstrated a slightly lower ICC; however, the associated absolute differences and Bland–Altman limits of agreement were small, within clinically acceptable margins, and not expected to affect annular sizing or overall clinical use.

Comprehensive subgroup analyses across CT scanner vendors, slice thickness, tube energy, reconstruction kernels, calcification severity, patient age, sex, and geographic distribution showed consistent performance. A lower ICC observed in a female-only subgroup was determined to be due to a single case with severe motion artifact and a very narrow measurement range, conditions under which ICC is not a reliable indicator of accuracy; absolute error and Bland–Altman results for the subgroup were consistent with the overall dataset. These isolated deviations were attributed to limitations on the quality of the input image rather than systematic algorithm behavior and do not impact device safety or effectiveness.

The optional aortic leaflet-coloring feature was evaluated separately using a multi-reader Likert-scale quality assessment, with over 93% of cases rated Good or Excellent, exceeding acceptance criteria. Overall, the bench testing demonstrated that the device performs as intended, with measurement accuracy comparable to expert clinical assessment, supporting substantial equivalence to the predicate device.

Conclusion on Non-Clinical Testing

The non-clinical testing of the CT TAVR Planning Assist demonstrated that the device delivers accurate and reliable measurements for key anatomical parameters relevant to TAVR planning. Performance validation using retrospective CT datasets confirmed strong agreement between the device outputs and clinician-generated ground truth measurements, with high intraclass correlation coefficients (ICC) across all measured parameters. The results indicate minimal bias and narrow confidence intervals, supporting the device's precision and consistency. Collectively, these findings confirm that the device's AI-assisted workflow is robust and suitable for its intended use in pre-procedural planning, meeting the established performance criteria without introducing new questions of safety or effectiveness.

IX. Substantial Equivalence Analysis Conclusion

The results of the non-clinical and performance validation testing demonstrate that the subject device is as safe and effective as the predicate device for its intended use. The TAVR planning measurements demonstrate robust agreement to clinician-generated ground truth, with no evidence of clinically significant bias or performance variability across subgroups. The aortic leaflet segmentation delivered consistently high visualization quality. These findings support the substantial equivalence of the device to the predicate devices, with no new questions of safety or effectiveness raised by its introduction. Therefore, the CT TAVR Planning Assist device meets the requirements for market clearance under the 510(k) pathway.