Circle Cardiovascular Imaging, Inc.
% Sydney Toutant
Regulatory Affairs Lead
Suite 1100 - 800 5th Ave. SW
Calgary, Alberta T2P 3T6
CANADA

January 18, 2023

Re: K222593
Trade/Device Name: TruPlan Computed Tomography (CT) Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: December 9, 2022
Received: December 9, 2022

Dear Sydney Toutant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222593

Device Name
TruPlan Computed Tomography (CT) Imaging Software

Indications for Use *(Describe)*
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 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.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K222593 - TruPlan 510(k) Summary

The following 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act 1990 and 21 CFR 807.92(c).

I. SUBMITTER

Submitter's Name:	Circle Cardiovascular Imaging, Inc.
Address:	Suite 1100 – 800 5th Ave SW, Calgary, AB, Canada, T2P 3T6
Date Prepared:	January 16 2023
Telephone Number:	+1 587 747 4692
Contact Person :	Sydney Toutant
Email:	sydney.toutant@circlecvi.com

II. DEVICE

Name of the Device:	TruPlan Computed Tomography (CT) Imaging Software
Short Brand Name:	TruPlan
Common or Usual Name:	Automated Radiological Image Processing System
Classification Name:	Medical image management and processing system
Proposed Classification:	Device Class: II Primary Product Code: QIH Secondary Product Code: LLZ Regulation Number: 21 CFR 892.2050

III. PREDICATE DEVICES

The primary predicate is the previously cleared version of TruPlan, manufactured by Circle CVI and cleared under K202212. 3mensio Workstation, manufactured by Pie Medical Imaging and cleared under K153736, is used as a secondary predicate.

The predicate devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The TruPlan Computed Tomography (CT) Imaging Software application ("TruPlan") is a software as a medical device that helps qualified users with image-based pre-procedural planning and post-procedural follow-up of the Left Atrial Appendage Closure (LAAC) procedure using CT data. TruPlan is designed to support the anatomical assessment of the Left Atrial Appendage (LAA) prior to and following the LAAC procedure. This includes the assessment of the LAA size, shape, and relationships with adjacent cardiac and extracardiac structures. This assessment helps the physician determine the size of a closure device needed for the LAAC procedure and evaluate LAAC device placement in a follow-up CT study. The TruPlan application is a visualization software and has basic measurement tools. The device is intended to be used as an aid to the existing standard of care and does not replace existing software applications physicians use for planning or follow-up for a LAAC procedure.

Pre-existing CT images are uploaded in TruPlan manually by the end-user. The images can be viewed by the user in the original CT image as well as simulated views. The software displays the views in a modular format as follows:

- Left Atrial Appendage (LAA)
- Fluoroscopy (Fluoro, simulation)
- Trans Esophageal Echo (TEE, simulation)
- Intra Cardiac Echography (ICE, simulation)
- Thrombus
- Follow-up
- Multiplanar Reconstruction (MPR)
- Reporting

These views offer the user visualization and quantification capabilities for pre-procedural planning and post-procedural follow-up of the LAAC procedure; none are intended for diagnosis. The quantification tools are based on user-identified regions of interest and are user-modifiable. The device allows users to perform the measurements (all done on MPR viewers) listed in **Table 1**, below.

TruPlan implements machine learning techniques to aid device use as follows:

1. **Left Heart Segmentation.** TruPlan generates a 3D rendering of the left side of the heart (including left ventricle, left atrium, and LAA) using machine learning methodology. The 3D rendering is for visualization purposes only; no measurement or annotations can be done using this view.
2. **Landing Zone Detection.** TruPlan uses machine learning techniques to initialize landing zone detection. No measurements are computed until the user reviews and corrects this initialization.

The data used to train TruPlan's machine learning algorithms were sourced from multiple clinical sites from urban centers and from different countries. The Left Heart Segmentation algorithm was trained on a total of 113 cases from the U.S., Canada, Germany, and other locations acquired using Siemens, GE, Toshiba, and Philips scanners where the left heart structures were manually

annotated by multiple expert readers. The Landing Zone Detection algorithm was trained on a total of 273 cases from various sites across the U.S. acquired using Siemens, GE, Toshiba, and Philips scanners where the landing zone was manually contoured by expert readers.

When selecting data for training, the importance of model generalization was considered and data was selected such that a good distribution of patient demographics, scanner, and image parameters were represented. The separation into training versus validation datasets is made on the study level to ensure no overlap between the two sets. As such, different scans from the same study were not split between the training and validation datasets. None of the cases used for model validation were used for training the machine learning models.

Table 1. TruPlan's measurement functionality and the specific module/workflow and measurement application for which it is used.

Measurement [units]	**Description**	**Module / Workflow**	**Application**
Distance [mm]	Length between two points, for both curved lines (splines) and straight lines, including the diameter (including min, max, average) resulting from closed splines and depth of the LAA	All modules	Diameter & depth of LAA landing zone (LAA module); distance between points of interest; diameter of a peri-device leak (Follow-up module)
Perimeter [mm]	The perimeter of a contour (closed spline)	All modules	Perimeter of LAA landing zone (LAA module); perimeter of other contours of interest
Area [mm^2]	The area within a contour	All modules	Area of LAA landing zone (LAA module); area of other contours of interest
Angle [degrees]	The angle of an object / structure of interest	All modules	Angle between two lines of interest
Signal intensity [HU]	Hounsfield value (in Hounsfield Units, HU) of the underlying pixels	All modules	Signal intensity of pixels in the regular vs. delayed scan (Thrombus module); average signal intensity within distal LAA (Follow-up module); intensity of other pixels of interest
Coordinates [mm, mm, mm]	Location in the x-, y-, and z-planes of a point	All modules	Coordinates of points of interest on a 3D rendering, for export purposes

These measurements are all manually placed by the user as annotations (overlays) and report the information calculated using the underlying pixels. TruPlan also provides reporting functionality to capture screenshots and measurements and to store them as a PDF document.

TruPlan is installed either as a standalone software onto the user's desktop or laptop computer, or as a server within the hospital infrastructure with a thick-client software on multiple users' desktop or laptop computers.

V. INDICATIONS FOR USE

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 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.

IMPORTANT: TruPlan is intended to be used as a pre-procedural planning aid, and LAAC procedures should be performed per the chosen LAAC device's approved IFU.

IMPORTANT: TruPlan is intended to be used as a post-procedural assessment aid, and all clinical decisions should be made per the chosen LAAC device's approved IFU.

VI. COMPARISON WITH PREDICATE DEVICES

The detailed analysis of the subject device and the primary and secondary predicate devices (shown in **Table 2** and **Table 3**) demonstrates that the subject device is substantially equivalent in indications for use / intended use, technological characteristics, functionality, and operating principles with the primary predicate (K202212) and with the secondary predicate (K153736). Of the three characteristics (technical, biological, and clinical) required for the demonstration of equivalence, biological characteristics are not applicable since the subject device and both predicate devices are software as a medical device application with no tangible component interfacing with the body.

Table 2. Indications for Use comparison to predicate devices.

Subject Device *TruPlan v3.0 (K222593)* Manufactured by Circle	**Primary Predicate** *TruPlan v1.0 (K202212)* Manufactured by Circle	**Secondary Predicate** *3mensio (K153736)* Manufactured by Pie Medical Imaging
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 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.	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. To facilitate the above, TruPlan provides general functionality such as: • Segmentation of cardiovascular structures • Visualization and image reconstruction techniques: 2D 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.	3mensio Workstation enables visualization and measurement of structures of the heart and vessels for: • Pre-operational planning and sizing for cardiovascular interventions and surgery • Postoperative evaluation • Support of clinical diagnosis by quantifying dimensions in coronary arteries • Support of clinical diagnosis by quantifying calcifications (calcium scoring) in the coronary arteries To facilitate the above, 3mensio Workstation provides general functionality such as: • Segmentation of cardiovascular structures • Automatic and manual centerline detection • Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMPR, Slabbing, MIP, AIP, MinIP • Measurement and annotation tools • Reporting tools

Table 3. Feature comparison to primary and secondary predicate devices.

Feature	**Subject Device** *TruPlan v3.0 (K222593)* Manufactured by Circle	**Primary Predicate** *TruPlan v1.0 (K202212)* Manufactured by Circle	**Secondary Predicate** *3mensio (K153736)* Manufactured by Pie Medical
Device Class	II	II	II
Device Classification	QIH LLZ	LLZ	LLZ
Regulation Name	Medical image management and processing system	Picture Archiving and Communications System	Picture Archiving and Communications System
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Input data type	CT data in DICOM format (vendor independent)	CT data in DICOM format (vendor independent)	CT data in DICOM (vendor independent)
Landing Zone Detection	Semi-automatic initialization of the landing zone using Machine Learning techniques; manual confirmation of the landing zone	Manual initialization and confirmation of the landing zone	Manual initialization and confirmation of the landing zone
Left Heart Segmentation	Semi-automatic segmentation for 3D visualization of the left heart using Machine Learning techniques; manual editing of 3D views possible	Semi-automatic segmentation for 3D visualization of the left heart using Machine Learning techniques; manual editing of 3D views possible	Semi-automatic segmentation for 3D visualization of the left heart; manual editing of 3D views possible
Study list image functionality	• Study/series previewing • Exporting • Deleting • Anonymizing • Search	• Study/series previewing • Exporting • Deleting • Anonymizing • Search	• Study/series previewing • Exporting • Deleting • Anonymizing • Search
Image assessment – simulated views	• 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	• 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	• Grayscale 3D rendering, to visualize relationship among LAAC procedure relevant anatomical structures • TEE, to provide similar views to intraprocedural TEE
Image assessment – other visualization functionality	• 2D • 3D (with manual & semi-automatic segmentation) • 4D (cine) • MPR • MIP • Annotations	• 2D • 3D (with manual & semi-automatic segmentation) • 4D (cine) • MPR • Annotations	• 2D • 3D (with manual & semi-automatic segmentation) • 4D (cine) • MPR • Annotations • Curved MPR • Stretch CMPR • Slabbing • MIP • AIP • MinIP • Centreline extraction • Calcium coring
Image assessment – measurement functionality	• Distance (length, diameter, perimeter) • Area • Angle • Signal intensity • Coordinates	• Distance (length, diameter, perimeter) • Area • Angle • Signal intensity • Coordinates	• Distance (length, diameter, perimeter) • Area • Angle • Signal intensity • Coordinates • Volume
Report functionality	• Patient/study information	• Patient/study information	• Patient/study information

Feature	Subject Device *TruPlan v3.0 (K222593)* Manufactured by Circle	Primary Predicate *TruPlan v1.0 (K202212)* Manufactured by Circle	Secondary Predicate *3mensio (K153736)* Manufactured by Pie Medical
	• Screenshots • Measurements • Free text • Device sizing table (for reference only) for LAA procedure	• Screenshots • Measurements • Free text • Device sizing table (for reference only) for LAA procedure	• Screenshots • Measurements • Free text • Device-specific reports for procedures covered in intended use
Operating system	Microsoft Windows Apple macOS	Microsoft Windows	Microsoft Windows
DICOM compliant	Yes	Yes	Yes

VII. PERFORMANCE DATA AND TESTING

Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485:2016, IEC 62304:2015, ISO 14971:2019, and NEMA 3.1-3.20 (2016) DICOM standards.

Verification and validation testing were conducted to ensure specifications and performance of the device and were performed per the FDA Guidance documents *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices"*. No clinical studies were necessary to support substantial equivalence.

TruPlan has been tested according to the specifications that are documented in a Master Software Test Plan. Testing is an integral part of Circle Cardiovascular Imaging Inc.'s software development as described in the company's product development process.

Validation of Machine Learning Derived Outputs

The machine learning algorithms of TruPlan (left heart segmentation, landing zone detection) have been trained and tested on images acquired from major vendors of CT imaging devices. All data used for validation were not used during the development of the training algorithms.

Across all CT machine manufacturers, n = 633 anonymized patient images were used for the validation of TruPlan. This translates into 533 samples (age and sex information unknown due to anonymization) for Left Heart Segmentation, and 100 samples (59 male and 41 female samples acquired from patients between 56 to 90+ years of age) for Landing Zone Detection. Image information for all samples was anonymized and limited to ePHI-free DICOM headers. The validation data was sourced from multiple sites across the U.S. and other urban regions. All performance testing results met Circle's pre-defined acceptance criteria.

- For the Left Heart Segmentation algorithm, the performance acceptance criteria were pre-defined to evaluate the performance of the ML model based on segmentation accuracy defined by probability of bone removal and probability of LAA visualization. The validation data was collected from the U.S., Canada, South America, Europe, and Asia acquired

using Siemens, GE, Toshiba, and Philips scanners. Bone was removed in 532/533 cases (99.81%); the LAA was correctly visualized by the rendering algorithm in 519/533 cases (97.37%).

- For the Landing Zone Detection algorithm, the performance acceptance criteria were pre-defined to evaluate the performance of the ML model based on detection accuracy defined by plane and contour center distance. The validation data was collected from various sites across the U.S., acquired using Siemens, GE, Toshiba, and Philips scanners. The landing zone was manually contoured by multiple expert readers for evaluation. Landing zone plane distance was within 10 mm in 97/100 cases (97%) with a mean distance of 3.87 mm; the landing zone contour center distance was within 12 mm in 99/100 cases (99%) with a mean distance of 2.92 mm.

VIII. CONCLUSIONS

The information submitted in this premarket notification, including the performance testing and predicate device comparisons, support the safety and effectiveness of TruPlan as compared to the predicate devices when used for the defined intended use.