Circle Cardiovascular Imaging Inc.
% Shirantha Samarappuli, Ph.D.
VP - Regulatory Affairs and QMS
Suite 1100-800 5th Ave SW
Calgary, Alberta T2P 3T6
CANADA

February 19, 2021

Re: K202212
Trade/Device Name: TruPlan Computed Tomography (CT) Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 15, 2021
Received: January19, 2021

Dear Dr. Samarappuli:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K202212

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.

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

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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TruPlan 510(k) Summary

K202212

I. SUBMITTER

Submitter's Name:	Circle Cardiovascular Imaging, Inc.
Address:	Suite 1100 – 800 5th Ave SW, Calgary, AB, Canada, T2P 3T6
Date Prepared:	January 13, 2021
Telephone Number:	+1 403 338 1870
Fax Number:	+1 403 338 1895
Contact Person:	Dr. Shirantha Samarappuli
Email:	shirantha.samarappuli@circlecvi.com

II. DEVICE

Name of the Device:	TruPlan Computed Tomography (CT) Imaging Software
Short Brand Name:	TruPlan
Common or Usual Name:	Image Processing System
Classification Name:	Picture Archiving and Communications System
Proposed Classification:	Device Class: II Product Code: LLZ Regulation Number: 21 CFR 892.2050

III. PREDICATE DEVICE

3mensio Workstation, manufactured by Pie Medical Imaging under K153736
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The TruPlan Computed Tomography (CT) Imaging Software application (referred to herein as "TruPlan") is a software as a medical device (SAMD) that helps qualified users with image-based pre-operative planning of Left Atrial Appendage Closure (LAAC) procedure using CT

data. The TruPlan device is designed to support the anatomical assessment of the Left Atrial Appendage (LAA) prior to 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. 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. It is not replacing the existing software applications physicians use for planning the Left Atrial Appendage Closure procedure.

Pre-existing CT images are uploaded in TruPlan application 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:

- LAA
- Fluoro (fluoroscopy, simulation)
- Trans Esophageal Echo (TEE, simulation)
- Intra Cardiac Echography (ICE, simulation)
- Thrombus
- Multiplanar Reconstruction (MPR)

Each of these views offer the user visualization and quantification capabilities for pre-procedural planning of the Left Atrial Appendage Closure 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.

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
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	Thrombus	Signal intensity of pixels in the regular vs. delayed scan; 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.

Additionally, the device 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 measurements or annotation can be done using this view.

TruPlan also provides reporting functionality to capture screenshots and measurements and to store them as a PDF document.

TruPlan is installed as a standalone software onto the user's Windows PC (desktop) or laptop (Windows is the only supported operating system). TruPlan does not operate on a server or cloud.

V. INDICATIONS FOR USE/ INTENDED 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.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

TruPlan is considered to be substantially equivalent to 3mensio Workstation (hereafter "3mensio"), a commercially available device manufactured by Pie Medical Imaging. Both devices enable visualization and quantification of the heart and cardiovascular structures and are intended for pre-procedural planning and sizing of the implantable device. Of the three characteristics (technical, biological, and clinical) required for the demonstration of equivalence, biological characteristics are not applicable since both TruPlan and 3mensio are standalone software applications with no tangible component interfacing with the body. Table 2 compares the individual features/characteristics for the two devices.

Table 2. Feature comparison table of TruPlan with the predicate device, 3mensio.

Feature / Characteristic	**New Device**	**Predicate Device**
General information		
Device name	TruPlan	3mensio
Manufacturer	Circle Cardiovascular Imaging	Pie Medical Imaging
510(k) number	K202212	K153736
Device Class	II	II
Device classification	LLZ	LLZ
Regulation Name	Picture Archiving and Communications system	Picture Archiving and Communications system
Regulation number	21 CFR 892.2050	21 CFR 892.2050
Indications for Use / Intended 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 To facilitate the above, TruPlan provides general functionality such as:	3mensio 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

	• 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.	(calcium scoring) in the coronary arteries To facilitate the above, 3mensio provides general functionality such as: • Segmentation of cardiovascular structures • Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMPR, slabbing, MIP, AIP, MinIP • Measurement and annotation tools • Reporting tools • Automatic and manual centerline detection
Technological Characteristics		
Input data type	CT data in DICOM format (vendor independent)	CT data in DICOM format (vendor independent)
Study list image functionality	• 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	• 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 • Annotations	• 2D • 3D (with manual & semi-automatic segmentation) • 4D (cine) • MPR • Annotations • Curved MPR • Stretch CMPR • Slabbing • MIP • AIP • MinIP • Centreline extraction • Calcium scoring
Image assessment – measurement functionality	• Distance (length, diameter, perimeter) • Area • Angle • Signal intensity • Coordinates	• Distance (length, diameter, perimeter) • Area • Angle • Signal intensity • Coordinates • Volume
Report functionality	• Patient/study information • Screenshots • Measurements • Free text • Device sizing table (for reference only) for LAA procedure	• Patient/study information • Screenshots • Measurements • Free text • Device-specific reports for procedures covered in intended use
Operating system	Microsoft Windows	Microsoft Windows
DICOM compliant	YES	YES

VII. PERFORMANCE DATA

Verification and validation activities were conducted to verify compliance with specified design requirements in accordance with applicable harmonized and consensus standards and following applicable FDA Guidance documents. Validated phantoms were used for assessing the quantitative measurement output of the device.

Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485:2016, IEC 62304:2015, IEC 62366:2015 and ISO 14971:2007.

DICOM conformance testing was performed to verify compliance with NEMA 3.1-3.20 (2011) 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.

VIII. CONCLUSIONS

The information submitted in this premarket notification, including the performance testing and predicate device comparisons, support the safety and effectiveness of the TruPlan software as compared to the predicate device, 3mensio (K153736).