TheraPanacea
% Mr. Edwin Lindsay
QA/RA Consultant
Pépinière Cochin Paris Santé
29 rue du Faubourg Saint-Jacques
Paris, 75014
FRANCE

January 14, 2021

Re: K202700
Trade/Device Name: ART-Plan
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QKB
Dated: December 9, 2020
Received: December 14, 2020

Dear Mr. Lindsay:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202700

Device Name
ART-Plan

Indications for Use *(Describe)*
ART-Plan is a software designed to assist the contouring process of the target anatomical regions on 3D-images of cancer patients for whom radiotherapy treatment has been planned.

The SmartFuse module allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison and delineation of image data by the user.

The images created with rigid or elastic registration require verifications, potential modifications, and then the validation of a trained user with professional qualifications in anatomy and radiotherapy.

With the Annotate module, users can edit manually and semi-automatically the contours for the regions of interest. It also allows to generate automatically, and based on medical practices, the contours for the organs at risk and healthy lymph nodes on CT images.

The contours created automatically, semi-automatically or manually require verifications, potential modifications, and then the validation of a trained user with professional qualifications in anatomy and radiotherapy.

The device is intended to be used in a clinical setting, by trained professionals only.

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.

K202700

TheraPanacea
Traditional 510(k)
For ART-Plan

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

TheraPanacea

Submitter's Address:

Pépinière Cochin Paris Santé
29 rue du Faubourg Saint-Jacques
75014 Paris
France

Telephone: +33 9 62 52 78 19

Establishment Registration Number:

Still to be established

Contact Person:

Edwin Lindsay

Telephone +44 (0) 7917134922

Date Prepared:

7th September 2020

TheraPanacea
Traditional 510(k)
For ART-Plan

Below summaries the Device Classification Information regarding the TheraPanacea ART-Plan:

Primary Product Code:

Regulation Number	Device	Device Class	Product Code	Classification Panel
892.2050	Medical device software, radiology	Class 2	QKB	Radiology

Device Trade Name:

ART-Plan

Device Common Name:

ART-Plan

Intended/ Indications Use:

ART-Plan is a software designed to assist the contouring process of the target anatomical regions on 3D-images of cancer patients for whom radiotherapy treatment has been planned.

The SmartFuse module allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison and delineation of image data by the user.

The images created with rigid or elastic registration require verifications, potential modifications, and then the validation of a trained user with professional qualifications in anatomy and radiotherapy.

With the Annotate module, users can edit manually and semi-automatically the contours for the regions of interest. It also allows to generate automatically, and based on medical practices, the contours for the organs at risk and healthy lymph nodes on CT images.

The contours created automatically, semi-automatically or manually require verifications, potential modifications, and then the validation of a trained user with professional qualifications in anatomy and radiotherapy.

The device is intended to be used in a clinical setting, by trained professionals only.

Summary of Substantial Equivalence:

The following predicate devices have been chosen that the ART-Plan can claim equivalence with and these are detailed below

General Comparison

		General Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
Common Name	Radiological image processing software for radiation therapy	Radiological image processing software for radiation therapy	System, image processing, radiological	System, image processing, radiological	System, image processing, radiological	N/A
Device Manufacturer	TheraPanacea	Xiamen Manteia Technology LTD	Mirada Medical Ltd.	Mirada Medical Ltd.	MIMvista Corp (now MIM Software Inc)	N/A
510k	N/A	K191928	K130393	K181572	K071964	N/A
Device Classification	II	II	II	II	II	N/A
Primary Product Code	QKB	QKB	LLZ	LLZ	LLZ	**As advised by the FDA the new product code, QKB, has been created in-lieu of LLZ which uses AI algorithms and is intended for radiation therapy, and is the proposed product code for ART-Plan.**
Secondary Product Code	-	-	-	-	-	N/A
Target Population	Any patient type for whom relevant modality scan data is available	Not stated	Any patient type for whom relevant modality scan data is available.	Any patient type for whom relevant modality scan data is available.	Not stated	**The proposed device has identical target populations to the secondary predicates.**
Environment	Hospital	Hospital	Hospital	Hospital	Hospital	**The proposed device and predicates have identical target environments**
Intended Use/ Indication for	**Intended Use** ART-Plan is a software designed	It is used by radiation oncology	Workflow Box is a system designed to allow users to route	RTx is intended to be used by trained medical	**Intended Use** MIM 4.1 (SEASTAR) software is intended for trained medical	**The intended use and indications for use of the proposed device, ART-Plan**

		General Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
Use	to assist the contouring process of the target anatomical regions on 3D-images of cancer patients for whom radiotherapy treatment has been planned. The SmartFuse module allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison and delineation of image data by the user. The images created with rigid or elastic registration require verifications, potential modifications, and then the validation of a trained user with professional qualifications in anatomy and radiotherapy. With the Annotate module, users can	department to register multimodality images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation.	DICOM-compliant data to and from automated processing components. Workflow Box includes processing components for automatically contouring imaging data using deformable image registration and machine learning based algorithms. Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components, for example image visualization software must be used to facilitate the review and edit of contours generated by Workflow Box component applications. Workflow Box is not intended to automatically detect lesions.	professionals including, but not limited to, radiologists, nuclear medicine physicians, radiation oncologists, dosimetrists and physicists. RTx is a software application intended to display and visualize 2D & 3D multi-modal medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include static and gated a, PET, MR, SPECT and planar NM. The user may also create, display, print, store and distribute reports resulting from interpretation of the datasets. RTx allows the user to register combinations of	professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists and physicists. MIM 4.1 (SEASTAR) is a medical image and information management system that is intended to receive, transmit, store, retrieve, display, print and process digital medical images, as well as create, display and print reports from those images. The medical modalities of these medical imaging systems include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM 4.1 (SEASTAR) provides the user with the means to display, register and fuse medical images from multiple modalities. Additionally, it evaluates cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction. The Region of Interest (ROI) feature reduces the time necessary for the user to define objects in medical image volumes by providing an initial definition of object contours. The objects include, but are not limited to, tumors and normal tissues.	**and the primary predicate AccuContour are the same in that they are software applications intended for professional use to display and visualize multi-modal medical image data. Supported modalities include CT, PET, and MR.** **The proposed device is also identical to the primary predicate in that it offers the same two key features of the planning process in radiotherapy: image registration and segmentation.** **In both devices, segmentation can only be performed on CT modality; registration can be done from every supported modality toward a CT with deformable registration.** **The proposed device may differ from the primary predicate in a) the list of structures included in automatic segmentation algorithm b) the presence or not of a rigid registration algorithm, which is a reduction compared to the deformable registration that is provided by ART-Plan. However, not enough information on these two aspects is provided on the**

		General Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
	edit manually and semi-automatically the contours for the regions of interest. It also allows to generate automatically, and based on medical practices, the contours for the organs at risk and healthy lymph nodes on CT images. The contours created automatically, semi-automatically or manually require verifications, potential modifications, and then the validation of a trained user with professional qualifications in anatomy and radiotherapy. The device is intended to be used in a clinical setting, by trained professionals only. .			anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison of image data by the user. The result of the registration operation can assist the user in assessing changes in image data; either within or between examinations and aims to help the user obtain a better understanding of the combined information that would otherwise have to be visually compared disjointedly. RTx provides a number of tools such as rulers and region of interests, which are intended to be used for the assessment of regions of an image to support a clinical workflow. Examples of such workflows include, but are not	MIM 4.1 (SEASTAR) provides tools to quickly create, transform, and modify contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems and archiving contours for patient follow-up and management. MIM 4.1 (SEASTAR) also aids in the assessment of PET/SPECT brain scans. It provides automated quantitative and statistical analysis by automatically registering PET/SPECT brain scans to a standard template and comparing intensity values to a reference database or to other PET/SPECT scans on a voxel by voxel basis, within stereotactic surface projections or standardized regions of interest. **<u>Indications for Use</u>** MIM 4.1 (SEASTAR) software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG,	**side of the primary predicate.**

		General Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
				limited to, the evaluation of the presence or absence of lesions, determination of treatment response and follow-up. RTx supports the loading and saving of DICOM RT objects and allows the user to define, import, display, transform, store and export such objects including regions of interest structures and dose volumes to radiation therapy planning systems. RTx allows the user to transform regions of interest associated with a particular imaging dataset to another, supporting atlas-based contouring and rapid re-contouring of the same patient.	US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM 4.1 (SEASTAR) assists in the following indications: * Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects. * Create, display and print reports from medical images. * Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning. * Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction. * Localization and definition of objects such as tumors and normal tissues in medical images. * Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management. * Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other	

		General Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
					registered PET/SPECT brain scans Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Images that are printed to film must be printed using a FDA-approved printer for the diagnosis of digital mammography images. Mammographic images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images. The software is not to be used for mammography CAD.	

System Information Comparison

	System Information					
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM 4.1 (SEASTAR)**	**Comment**
Method of Use	Standalone software application accessed via a compliant browser (Chrome or Mozilla Firefox) on a personal computer, tablet or phone (In case of connection to the platform with a screen of a phone or a tablet, the user must choose the option for the desktop site of his communication device. The platform is optimally used with 17 inches and up screen. Facilitates display and visualization of data by user.	Standalone software	Standalone software application	Standalone software application	Standalone software package	**The proposed device and predicates have identical methods of use**
Computer Platform and Operating System	Full web platform Launch from Google Chrome or Mozilla Firefox	Windows	Workstation and Server based application supporting Windows Server 2008 R2,	Server based application supporting Microsoft Windows 10 (64-bit) and Microsoft	Windows 2000/XP	**The proposed devices and predicates are compatible with identical operating systems**

	System Information					
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM 4.1 (SEASTAR)**	**Comment**
			SP1 and Windows 7 (64-bit)	Windows Server 2016.		
Data Visualization / Graphical Interface	Yes	Yes	Yes	None – the proposed device has no data visualization functionality. All data processing is automated and does not require user interaction. A control interface is provided for system administration and configuration only.	Yes	**The proposed device is identical to the primary predicate, and secondary predicate, MIM 4.1, in that it has a graphical interface.** **Workflow Box is AI based but has no interface. RTx is not AI based but has an interface and thus most of the tools of Annotate for contour edition/display**
Supported Modalities	**Registration**: Static and gated CT, MR, PET (via the registration of the CT of said PET) **Segmentation**: CT (injected or not), DICOM RTSTRUCT	**Registration:** Multimodality DICOM fixed and moving images including CT, MR, PET **Segmentation:** Non-contrast CT	Static and gated CT and PET, MR, SPECT, NM, DICOM RT	CT, MR, DICOM RTSTRUCT for image processing Any valid DICOM data for data routing	Medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0.	**The proposed device is compatible with the same modalities as the primary predicate on the registration feature, which are CT, MR and PET images in a DICOM format. For both devices, supported images can be fixed (static) or moving (gated).** **The primary predicate device and ART-Plan are both compatible only with CT images on the segmentation feature. The predicate device claims to handle only non-injected CTs while ART-Plan can be used with injected CT images as well.** **The predicate device does not**

	System Information					
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM 4.1 (SEASTAR)**	**Comment**
						explicitly mention the format RTStruct in supported modalities which correspond to the format used to store segmentation masks in radiotherapy. The terms "medical images and DICOM data" are used by the primary predicate device, which can imply the management of DICOM RTStruct. **Compared to secondary predicates, ART-Plan claims less supported modalities.**
Data Export	Distribution of DICOM compliant Images into other DICOM compliant systems.	Allows export of medical images and DICOM data	Distribution of DICOM compliant Images into other DICOM compliant systems.	Supports routing and distribution of images to other DICOM nodes including to custom executables determined by the user.	The system has the ability to send data to DICOM-ready devices for image storage, retrieval and transmission.	**The proposed device and primary predicates have identical data export capabilities.**
Comtibility	Compatible with data from any DICOM compliant scanners for the applicable modalities.	No Limitation on scanner model, DICOM 3.0 compliance required. Compatible with Microsoft Windows.	Compatible with data from any DICOM compliant scanners for the applicable modalities.	Compatible with data from any DICOM compliant scanners for the applicable modalities. Integration with Mirada DBx application launcher	The software can receive, transmit, store, retrieve, display, print, and process DICOM objects and medical image modalities including, but not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0.	**The proposed device and primary predicates have identical compatibilities**

	System Information					
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM 4.1 (SEASTAR)**	**Comment**
		No Limitation on treatment planning system (TPS) model, DICOM 3.0 compliance required.		and data browser		

Technical Information Comparison

		Technical Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
Delineation Method	AI	AI	Atlas	AI	Atlas	**The proposed device, primary predicate and secondary predicate Workflow Box share an AI delineation method.**
Image registration	Multi-modal and mono-modal. Rigid and deformable Automatic and manual initialization (landmarks, fusion box, alignment). Registration for the purposes of replanning/ recontouring and AI-based automatic contouring.	Automatic registration. Multi-modal and mono-modal. Deformable registration. Intensity based algorithm Registration for the purpose of treatment planning, treatment evaluation and treatment adaptation.	Manual and Landmark Rigid. Automatic multi-modal rigid. Mono-modal and multi-modal deformable registration. Motion correction in hybrid scans and gated scans. Registration for the purposes of replanning/recontouring and atlas-based contouring.	Registration for the purposes of replanning/ re-contouring and AI based contouring. The algorithms used for image registration are the same for both RTx and Workflow Box devices.	Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning.	**Both the predicate device and ART-Plan offer mono-modal (CT-CT) and multi-modal (CT/MR, CT/PET) deformable registration.** **The SmartFuse module of ART-Plan also offers rigid registration, which is a reduction of the deformable registration since the degree of freedom of the transformation are constrained.** **Both devices offer an automatic solution for registration. ART-Plan also offers semi-automatic registration by including manual initialization tools in addition to automatic initialization.** **Secondary devices offer the same options as the proposed device: rigid and deformable transformation. No information is given on the possible automatization of this process.**
Segmentation Features	Automatically delineates OARs and healthy lymph nodes (on any	Automatically delineates OAR (on non-contrast CT images)	Automatically delineates any structure (OAR or lymph node) included in the atlas	Not stated.	The software automatically generates contours using a deformable registration technique which registers pre-contoured patients to target patients.	**The proposed device and primary predicate are capable of automatically contouring the organ-at-risk (OAR).**

		Technical Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
	CT images) Deep learning algorithm. Automatic segmentation includes the following localizations: * head and neck * thorax/breast (for male/female) * abdomen * pelvis (for male only) * brain.	Deep learning algorithm. It can automatically contour the organ-at-risk, including head and neck, thorax, abdomen and pelvis (for both male and female),	images. Atlas algorithm (contour registration) Automatic segmentation supports any anatomy included in atlas images.		Registrations are either between a serial pair of intra-patient volumes or between a pre-existing atlas of contoured patients and a patient volume. This process facilitates contour creation or re-contouring for adaptive therapy.	**They differ in that ART-Plan can also delineate healthy lymph nodes.** **Plus, there is a difference in intended anatomies. The common localizations are the head and neck, thorax, abdomen and male pelvis. ART-Plan does not claim to offer automatic segmentation on female pelvis. However, in addition to the 4 upper common localizations, ART-Plan can also be used for brain localizations.** **Secondary predicate using atlas-based algorithms can be applied on any localization and for any type of structure contained in atlas images used by the center.**
View Manipulation and Volume Rendering	Window and level, pan, zoom, cross-hairs, slice navigation. Maximum, average and minimum intensity projection (MIP, AVG, MinIP), color rendering, multi-planar reconstruction (MPR), fused views, gallery views.	Not stated	Window and level, pan, zoom, cross-hairs, slice navigation. Maximum or minimum intensity projection (MIP), volume rendering, color rendering, surface rendering, multi-planar reconstruction (MPR), fused views, gallery views.	None – Not applicable	Not stated	**No information has been found regarding view manipulation and volume rendering concerning the primary predicate. The predicate device claims to offer a feature to review the processed image and perform manual contouring, which implies at least the display of DICOM images with slice navigation.** **The proposed device has the majority of the same tools as the secondary RTx predicate, apart from volume and surface**

		Technical Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
						rendering **The Workflow Box secondary predicate does not offer a graphical interface.**
Regions and Volumes of Interest (ROI)	AI Based autocontouring, Registration based contour projection (re-contouring), Manual ROI manipulation and transformation (margins, booleans operators, interpolation).	Automatic target volume delineation system. Automatically delineates organs-at-risk (OAR) Manual Contour	2D and 3D ROIs, semi-automatic ROI definition, isocontour ROIs using threshold and percentage of maximum, one-click seed-pointing contouring, manual ROI manipulation, ROI transformation, Atlas-based contouring.	Atlas Based contouring, registration based recontouring, machine learning based contouring	Atlas based contouring, tools to quickly create, transform, and modify contours.	**Both the proposed device and the primary predicate allow AI automatic contouring and manual contouring**
Region/volume of interest measurements and size measurements	Intensity, Hounsfield units and SUV measurements Size measurements include 2D and 3D measurements (number of slices, volume of a structure, static ruler)	Not stated	Intensity, Hounsfield units, activity and SUV measurements including min, max, mean, peak, standard deviation, total glycolytic activity, median, histogram, max and mean ratio to reference region. Gray for RT Dose. Size measurements include 2D and 3D measurements including rulers and volume, line profile.	None – not applicable	Quantitative analysis tools.	**ART-Plan offers the same Intensity, Hounsfield units and SUV measurements and size measurements including 2D and 3D measurements (volume and ruler) as secondary predicate RTx. However, this is only a fraction of the tools claimed by secondary predicate RTx.**

		Technical Information				
Property	***Proposed Device*** **ART-Plan**	***Primary Predicate*** **AccuContour**	***Secondary Predicate*** **RTx**	***Secondary Predicate*** **Workflow Box**	***Secondary Predicate*** **MIM4.1 (SEASTAR)**	**Comment**
Region/Volume Quantification	None	Not stated	Regions table with charting supports analysis of measurement over multiple studies using standard protocols such as RECIST, PERCIST and WHO	None – not applicable	Quantitative analysis tools.	**The secondary predicate RTx offers a range of tools for region/volume quantification. ART-Plan does not offer these kinds of tools. It is a reduction in claim or equivalent to the primary predicate for which no information was found.**

Device Description:

The ART-Plan application is comprised of two key modules: SmartFuse and Annotate, allowing the user to display and visualize 3D multi-modal medical image data. The user may process, render, review, store, display and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include static and gated CT (computerized tomography), PET (positron emission tomography), and MR (magnetic resonance).

The overview of the product, in terms of input/output, functionalities and integration within the current clinical workflow for radiation therapy planning.

The ART-Plan technical functionalities claimed by TheraPanacea are the following:

- Proposing automatic solutions to the user, such as an automatic delineation, automatic multimodal image fusion, etc. towards improving standardization of processes/ performance / reducing user tedious / time consuming involvement.
- Offering to the user a set of tools to assist semi-automatic delineation, semi-automatic registration towards modifying/editing manually automatically generated structures and adding/removing new/undesired structures or imposing user-provided correspondences constraints on the fusion of multimodal images.
- Presenting to the user a set of visualization methods of the delineated structures, and registration fusion maps.
- Saving the delineated structures / fusion results for use in the dosimetry process.
- Enabling rigid and deformable registration of patients images sets to combine information contained in different or same modalities.

Technological Characteristics:

A comparative review of the ART-Plan with the predicate device found that the technology, mode of operation, and general principles for treatment with this device were substantially equivalent.as the predicate device.

Non-Clinical Tests (Performance/Physical Data):

The ART-Plan was evaluated for its safety and effectiveness based on the following testing:

Test Name	Test Description	Results
Usability Testing	The ART-Plan was assessed with regards to usability for compliance with IEC 62366	Passed
Autosegmentation performances	The study gathers the information on the 3 tests performed on the automatic segmentation performances on European data.	Passed

Test Name	Test Description	Results
Autosegmentation performances according to AAPM requirements	The testing demonstrated that the auto-segmentation algorithm of the module Annotate provides acceptable contours for the concerned structures on an image of a patient.	Passed
Autosegmentation performances against MIM	The testing demonstrated that the auto-segmentation algorithm of the module Annotate provides acceptable contours for the concerned structures on an image of a patient.	Passed
Qualitative validation of autosegmentation performances	The testing demonstrated that the auto-segmentation algorithm of the module Annotate provides acceptable contours for the concerned structures on an image of a patient.	Passed
External Contour performances according to AAPM requirements	The testing demonstrated that the External Contour Automatic Segmentation algorithm of the module Annotate provides acceptable contours for the patient's body on an image of a patient.	Passed
Fusion performances according to AAPM recommendations	The testing evaluated the quality of the rigid and deformable registration tools of the SmartFuse module on retrospective intra-patient images and inter-patient images of different modalities, to ensure the safety of the device for clinical use.	Passed
Registration performances on POPI-model	The testing evaluated the quality of the deformable registration tools of the SmartFuse module on intra-patient CT images. Testing was conducted according to POPI-model protocol on corresponding public data.	Passed

Test Name	Test Description	Results
Autosegmentation performances on US data	The testing demonstrated that the autosegmentation algorithm of the Annotate module provides clinically acceptable contours for the concerned structures when applied to US patients.	Passed
Pilot study for sample size estimation - literature review	The testing was a pilot study estimating a consistent sample size of dataset for our performance testing's considering the state-of-art studies in image registration and segmentation. The literature review was completed on the most cited articles in the field of medical vision.	Passed
System Verification and Validation Testing	The system verification and validation testing was performed to verify the software of the ART-Plan.	Passed

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The software for this device was considered as a "major" level of concern, since a failure or latent design flaw could directly result in death or serious injury to the patient or a failure or provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death.

Animal Studies

No animal studies were conducted as part of submission to prove substantial equivalence.

Clinical Studies

No clinical studies were conducted as part of submission to prove substantial equivalence.

Safety and Effectiveness/Conclusion:

Based on the information presented in these 510(k) premarket notifications the TheraPanacea ART-Plan is considered substantially equivalent.

Based on testing and comparison with the predicate devices, TheraPanacea ART-Plan indicated no adverse indications or results. It is our determination that the TheraPanacea ART-

Plan is safe, effective and performs within its design specifications and is substantially equivalent to the predicate device.