December 23, 2025

Therapanacea SAS
Ajachandra Bhairavi
Design & Compliance Director
7 bis boulevard Bourdon
Paris, 75004
France

Re: K253091
Trade/Device Name: ART-Plan+ (v3.1.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ, QKB, LLZ
Dated: September 23, 2025
Received: September 23, 2025

Dear Ajachandra Bhairavi:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253091

Please provide the device trade name(s).

ART-Plan+ (v3.1.0)

Please provide your Indications for Use below.

ART-Plan+'s indicated target population is cancer patients for whom radiotherapy treatment has been prescribed. In this population, any patient for whom relevant modality imaging data is available.

ART-Plan+'s includes several modules:

SmartPlan which allows automatic generation of radiotherapy treatment plan that the users import into their own Treatment Planning System (TPS) for the dose calculation, review and approval. This module is available for supported prescriptions for prostate only.

Annotate which allows automatic generation of contours for organs at risk, lymph nodes and tumors, based on medical practices, on medical images such as CT and MR images

AdaptBox which allows generation of synthetic-CT from CBCT images, dose computation on CT images for external beam irradiation with photon beams and assisted CBCT-based off-line adaptation decision-making for the following anatomies

Head & Neck

Breast / Thorax

Pelvis (male)

ART-Plan+ is not intended to be used for patients less than 18 years of age.

The indicated users are trained medical professionals including, but not limited to, radiotherapists, radiation oncologists, medical physicists, dosimetrists, and medical professionals involved in the radiation therapy process.

The indicated use environments include, but are not limited to, hospitals, clinics and any health facility offering radiation therapy.

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)

K253091

TheraPanacea SAS
Traditional 510(k)
ART-Plan+

510(k) Summary

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

Contact details

Applicant Name:

TheraPanacea SAS

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Applicant Contact:

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Device Name:

Device Trade Name	Regulation Number	Common name	Device Class	Product Code(s)	Classification Name
ART-Plan+ (v3.1.0)	892.5050	Medical charged-particle radiation therapy system	Class II	MUJ Associated Product Code(s): QKB, LLZ	System, Planning, Radiation Therapy Treatment

Legally marketed predicate device

Predicate #	Predicate trade name (primary predicate is listed first)	Product code
K242822	ART-Plan	MUJ

Legally marketed reference devices

Reference device #	Reference device trade name	Product code
K234068	ART-Plan	MUJ

Device Description Summary:

ART-Plan is a software platform allowing contour regions of interest on 3D images, to provide an automatic treatment plan and to help in the decision for the need for replanning based on contours and doses on daily images. It includes several modules:

Home: tasks and patient monitoring

Annotate including TumorBox: contouring of regions of interest

Smartplan: creation of an automatic treatment plan based on a planning CT and a RTSS

AdaptBox: helping tool to decide if a replanning is necessary. For this purpose, the module allows the user to generate a synthetic-CT from a CBCT image, to auto-delineate regions of interest on the synthetic-CT, to compute the dose on both planning CT and synthetic-CT and then define if there is a need for replanning by comparing volume and dose metrics computed on both images and over the course of the treatment. Those metrics are defined by the user.

Administration and Settings: preferences management, user account management, etc.

About: information about the software and its use, as well as contact details.

Annotate, TumorBox, Smartplan and AdaptBox are partially based on a batch mode, which allows the user to launch the operations of autocontouring and autoplanning without having to use the interface or the viewers. In that way, the software is completely integrated into the radiotherapy workflow and offer to the user a maximum of flexibility.

Annotate which allows automatic generation of contours for organs at risk (OARs), lymph nodes (LNs) and tumors, based on medical practices, on medical images such as CT and MR images:

OARs and LNs:

- Head and neck (on CT images)
- Thorax/breast (on CT images)
- Abdomen (on CT and male on MR images)
- Pelvis male (on CT and MR images)

- Pelvis female (on CT images)
- Brain (on CT images and MR images)

Tumor:

- Brain (on MR images)

SmartPlan which allows automatic generation of radiotherapy treatment plan that the users import into their own Treatment Planning System (TPS) for the dose calculation, review and approval. This module is available for supported prescriptions for prostate only.

AdaptBox which allows generation of synthetic-CT from CBCT images, dose computation on CT images for external beam irradiation with photon beams and assisted CBCT-based off-line adaptation decision-making for the following anatomies

o Head & Neck

o Breast / Thorax

o Pelvis (male)

Intended Use/Indication for use:

ART-Plan+'s indicated target population is cancer patients for whom radiotherapy treatment has been prescribed. In this population, any patient for whom relevant modality imaging data is available.

ART-Plan+'s includes several modules:

- SmartPlan which allows automatic generation of radiotherapy treatment plan that the users import into their own Treatment Planning System (TPS) for the dose calculation, review and approval. This module is available for supported prescriptions for prostate only.
- Annotate which allows automatic generation of contours for organs at risk, lymph nodes and tumors, based on medical practices, on medical images such as CT and MR images
- AdaptBox which allows generation of synthetic-CT from CBCT images, dose computation on CT images for external beam irradiation with photon beams and assisted CBCT-based off-line adaptation decision-making for the following anatomies:
    - Head & Neck
    - Breast / Thorax
    - Pelvis (male)

ART-Plan+ is not intended to be used for patients less than 18 years of age.

The indicated users are trained medical professionals including, but not limited to, radiotherapists, radiation oncologists, medical physicists, dosimetrists, and medical professionals involved in the radiation therapy process.

The indicated use environments include, but are not limited to, hospitals, clinics and any health facility offering radiation therapy.

Indication for use comparison:

The intended use of the proposed device, ART-Plan+ v3.1.0, the primary predicate and the reference device are similar as they are both softwares intended to be used in the planning of radiotherapy treatment:
- they allow creation of contours (same as primary predicate and reference device)
- they allow the user to import the generated plan into their own Treatment Planning System (TPS) for dose calculation, review and approval (same as primary predicate)
- they allow the user to generate synthetic CT from CBCT, dose computation on CT images for external beam irradiation with photon beams and offer assisted CBCT-based off-line adaptation decision-making (same as reference device).

The indications for use of the proposed device ART-Plan+ v3.1.0 is equivalent to the one of the primary predicate.

An additional bullet point detailing the anatomies on which AdaptBox can perform has been added. This additional bullet point included within the proposed device and related to AdaptBox, it is in fact covered by the reference's device (of which the proposed device is an update) intended use as they both allow the user to generate synthetic CT from CBCT, dose computation on CT images for external beam irradiation with photon beams and offer assisted CBCT-based off-line adaptation decision-making (same as reference device).

Technological Comparison:

The similarities between the proposed device and the primary predicate are the following:

- Both devices allow automatic generation of contours for organs at risk, lymph nodes and tumors, based on medical practices, on medical images such as CT and MR images

- Both allow automatic generation of radiotherapy treatment plan for supported prescriptions and anatomies that the users import into their own Treatment Planning System (TPS) for the dose calculation, review and approval

The differences between the proposed device and the primary predicate are:

- The module AdaptBox (see the bullet points below) which is covered by the reference device ART-Plan v2.2.0 which is the previous version cleared of both the primary predicate ART-Plan+ 3.0.0 and the proposed device ART-Plan+ 3.1.0:

    - Both devices allow generation of synthetic-CT from CBCT images

- Both allow dose computation on CT and/or synthetic-CT images for external beam irradiation with photon beams

- Both allow assisted CBCT-based off-line adaptation decision-making for supported anatomies

- Addition of new structures to the already existing localizations to the segmentation feature (ribs, cauda equina, prostate CTVn), improvement of existing structures to the segmentation feature and extension of existing anatomy to the use of brachytherapy within radiotherapy.

- Improvement of the prescription coverage of SmartPlan for the existing anatomy of Prostate.

There are no differences between the proposed device and the primary predicate or the reference device that represent an additional claim for the proposed device.

System Information Comparison				
Property	***Proposed Device*** **ART-Plan+ v3.1.0**	***Primary Predicate*** **ART-Plan+ v3.0.0**	***Reference Device n°2*** **ART-Plan v2.2.0**	**Comment**
Method of Use	Standalone software application accessed via a compliant browser (Chrome, Mozilla Firefox and Edge) 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 application accessed via a compliant browser (Chrome, Mozilla Firefox and Edge) 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 application accessed via a compliant browser (Chrome, Mozilla Firefox and Edge) 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.	The proposed device, the primary predicate and the reference devices are standalone software.
Delineation Method	AI	AI (deep learning neural networks)	AI	The proposed device, primary predicate and the reference devices share an AI delineation method.
Synthetic CT	Generation of CT density image series out of CBCT images	Not applicable	Generation of CT density image series out of multiple MR-image series and CBCT images	The proposed device and reference device share the same module named AdaptBox that can generate synthetic-CT from CBCT images.
Dose computation	Dose computation on CT and/or synthetic-CT images for external beam irradiation with photon beams	Not applicable	Dose computation on CT and/or synthetic-CT images for external beam irradiation with photon beams	The proposed device and the reference device share the same module named AdaptBox that can perform dose computation.

Off-line adaptation decision-making	Assisted CBCT-based off-line adaptation decision-making for supported anatomies	Not applicable	Assisted CBCT-based off-line adaptation decision-making for supported anatomies	The proposed device and the reference device share the same module named AdaptBox that can assist off-line adaptation decision-making.
Supported Modalities for segmentation	**Segmentation**: CT (injected or not), MR images, DICOM RTSTRUCT, synthetic-CT from CBCT	**Segmentation**: CT (injected or not), MR images, DICOM RTSTRUCT, synthetic-CT from CBCT	**Segmentation**: CT (injected or not), MR images, DICOM RTSTRUCT, synthetic-CT from CBCT	The proposed device, the primary predicate and the reference devices propose segmentation on medical images of different modalities.
Data Export	Distribution of DICOM compliant Images into other DICOM compliant systems.	Distribution of DICOM compliant Images into other DICOM compliant systems.	Distribution of DICOM compliant Images into other DICOM compliant systems.	The proposed device, the primary predicate and the reference devices have identical data export capabilities with DICOM format.
Compatibility	Compatible with data from any DICOM compliant systems for the applicable modalities.	Compatible with data from any DICOM compliant systems for the applicable modalities.	Compatible with data from any DICOM compliant scanners for the applicable modalities.	The proposed device, the primary predicate and the reference devices have identical compatibility (DICOM format)

Technical Information				
Property	***Proposed Device*** **ART-Plan v3.1.0**	***Primary Predicate ART-Plan v3.0.0***	***Reference Device*** **ART-Plan v2.2.0**	**Comment**
Segmentation Features	Automatically delineates OARs and lymph nodes and targets. Deep learning algorithm. Automatic segmentation includes the following localizations: *head and neck (on CT and synthetic-CT from CBCT images) *thorax / breast (for male/female and on CT and synthetic-CT from CBCT images) *abdomen (on CT images and MR images) *pelvis male (on CT, MR and synthetic-CT from CBCT images) *pelvis female (on CT and MR images) *brain (on CT images and MR images)	Automatically delineates OARs and lymph nodes and targets. Deep learning algorithm. Automatic segmentation includes the following localizations: * head and neck (on CT) * thorax/breast (for male/female and on CT) * abdomen (on CT images and MR images) * pelvis male (on CT and MR) * pelvis female (on CT images) * brain (on CT images and MR images)	Automatically delineates OARs and lymph nodes Deep learning algorithm. Automatic segmentation includes the following localizations: * head and neck (on CT and synthetic-CT from CBCT images) * thorax/breast (for male/female and on CT and synthetic-CT from CBCT images) * abdomen (on CT images and MR images) * pelvis male (on CT, MR and synthetic-CT from CBCT images) * pelvis female (on CT images) * brain (on CT images and MR images)	The proposed device, the primary predicate and also the reference device (when it comes to segmentation on synthetic-CT from CBCT image used within the shared module, AdaptBox) propose segmentation on the same localizations with the same medical images of different modalities using AI.

Regions and Volumes of Interest (ROI)	AI Based autocontouring	AI Based autocontouring	AI Based autocontouring Registration based contour projection (re-contouring) Manual ROI manipulation and transformation (margins, booleans operators, interpolation).	The proposed device, the primary predicate and the reference devices allow AI automatic contouring.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Annotate, SmartPlan and AdaptBox are three separate modules, each sold under its own independent license. Users can opt to purchase either Annotate, SmartPlan or AdaptBox individually or even many modules with specific license for each module, based on their specific needs.

Annotate is designed for segmentation workflows, enabling an end-to-end process where images are sent to be contoured, and the resulting contours are returned in RTSS format. On the other hand, SmartPlan takes the patient's CT image and approved set of structures (RTSS) as input and generates a potentially deliverable treatment plan (RTPLAN). These RTSS files not only include contours of organ at risks (OARs) and lymph nodes (LNs) s but also tagerts that can be created by clinicians using other devices than ART-Plan's Annotate module. Similarly, AdaptBox is a helping tool to decide if a replanning is necessary. For this purpose, the module allows the user to generate a synthetic-CT from a CBCT image, to auto-contour regions of interest on the synthetic-CT using Annotate or to propagate contours from the planning CT to the synthetic-CT by registration without using Annotate, to compute the dose on both planning CT and synthetic-CT and then define if there is a need for replanning by comparing volume and dose metrics computed on both images and over the course of the treatment. Those metrics are defined by the user.

As we are doing retrospective non-clinical performance testing, all the steps of the workflow where ART-Plan is involved have been tested independently.

In order to determine the substantial equivalence of ART-Plan + v3.1.0, the following tests have been performed:

Annotate: The contours are considered acceptable for clinical use if one of the test passes:

Non regression testing of autosegmentation - Validation of the performance of autosegmentation (on CT and MR images) of already existing structures after retraining or algorithm improvement was performed by comparison of the DSC between contours generated by the previous version of ART-Plan and manual contours performed by medical experts and the DSC between contours generated by the new version of ART-Plan + (v3.1.0) and manual contours performed by medical experts. The evaluation was performed on a minimum sample

size of 24 patients. The contours are considered acceptable for clinical use if the following acceptance criterion is achieved:

- **Mean DSC should not regress negatively between the current and last validated version of Annotate beyond a maximum tolerance margin set to -5% relative error.**

For the specific case of autosegmentation on synthetic-CT from CBCT images, the validation of the performance of autosegmentation of already existing structures after autosegmentaiton or synthetic CT generation algorithms retraining or improvement was performed by comparison of the DSC obtained with contours generated on CT images and the DSC obtained on contours generated on synthetic CT from CBCT images. The evaluation was performed on a minimum sample size of 24 patients.
The contours are considered acceptable for clinical use if the following acceptance criterion is achieved:

- **Mean DSC (sCT) should be equivalent to Mean DSC (CT) beyond a maximum tolerance margin set to -5% relative error.**

OR

Qualitative evaluation of autosegmentation - Validation of the performance of autosegmentation of new structures (or structures not passing the non regression testing) on CT, MR & synthetic-CT from CBCT images was performed by qualitative evaluation of the contours by medical experts. This evaluation was performed on a minimum sample size of 18 patients.
The contours are considered acceptable for clinical use if the following acceptance criterion is achieved:

- **The clinicians' qualitative evaluation of the auto-segmentation is considered acceptable for clinical use without modifications (A) or with minor modifications / corrections (B) with a A+B % above or equal to 85% considering the following scale:**
  A. **the contour is acceptable for a clinical use without any modification**
  B. **the contour would be acceptable for clinical use after minor modifications/corrections**
  C. **the contour requires major modifications (e.g. it would be faster for the expert to manually delineate the structure)**

OR

Quantitative evaluation of autosegmentation – validation of the performance of autosegmentation of new structures on CT, MR images was performed by quantitative evaluation of the contours. This evaluation was performed on a minimum sample size of 24 patients.
The contours are considered acceptable for clinical use if the following acceptance criterion is achieved:

- **Mean DSC (annotate) ≥ 0.8**

SmartPlan: The treatments plans are considered acceptable for clinical use if both tests (quantitative and qualitative) pass:

Quantitative and qualitative evaluation of automatic treatment plans generations – validation of the performance of automatic radiotherapy treatment plans generation was performed by both quantitative and qualitative evaluation. The quantitative evaluation consisted of direct comparison with manual plans. The qualitative evaluation consisted of medical

experts determining the clinical acceptability of plans. These evaluations were performed on a minimum sample size of 20 patients.
The treatments plans are considered acceptable for clinical use if the following acceptance criteria are achieved:

- Quantitative evaluation: **effectiveness difference (%) in DVH achieved goals between manual plans and automatic plans ≤ 5%**

AND

- Qualitative evaluation: **% of clinical acceptable automatic plans ≥ 93%** after expert review.

AdaptBox: Features of AdaptBox are considered acceptable for clinical use if they pass the associated acceptance criteria:

Dosimetric evaluations of synthetic CT from CBCT images – validation of the performance of the synthetic CT from CBCT images was performed by dosimetric evaluation. The dosimetric evaluation consisted of dosimetric endpoints comparison with standard CT. These evaluations were performed on a minimum sample size of 15 patients.
The synthetic-CT from CBCT feature in AdaptBox module produces is considered acceptable for clinical use if the following acceptance criteria are achieved:

- **Median 2%/2mm ≥ 92%**

AND

- **Median 3%/3mm ≥ 93.57%**

AND

- **A median dose deviation (synthetic-CT compared to standard CT) of ≤2% in ≥76.7% of patients**

Quantitative validation of synthetic CT from CBCT images – validation of the performance of the synthetic CT from CBCT images was performed by anatomic and geometric evaluation. The evaluation consisted of direct comparison of anatomy and geometry with the associated CBCT. These evaluations were performed on a minimum sample size of 15 patients. (Note that this evaluation has also been performed on a independent dataset composed only of US patients)
The treatments plans are considered acceptable for clinical use if the following acceptance criteria are achieved:

- **Jacobian determinant = 1 +/- 5%**

Qualitative validation of deformation of planning CT towards CBCT images – validation of the performance of the deformation of planning CT images was performed by qualitative evaluation. The evaluations were performed on a minimum sample size of 10 patients.
The deformed planning CT are considered acceptable for clinical use if the following acceptance criteria are achieved:

- The clinicians' qualitative evaluation of the overall registration output following clinical protocols to qualitatively assess registration outcomes is considered acceptable for clinical use with **A+B% above or equal to 85%** for deformable considering the following scale:

A. The registration exceeds the expectation
B. The registration meets the expectation (incl. cases for which additional margin may be required or registration might be relaunched using different supporting tools)
C. The registration is not acceptable

Qualitative validation of deformable propagation of contours from planning CT to synthetic CT from CBCT images – validation of the performance of the propagation of contours

- The clinicians' qualitative evaluation of the propagated contours post-registration are considered acceptable for clinical with **A+B% above or equal to 85%** considering the following scale:

A. The contour is acceptable for a clinical use without any modification
B. The contour would be acceptable for clinical use after minor modification / corrections
C. The contour requires major modifications (e.g. it would be faster for the expert to manually delineate the structure)

All validation tests were carried out using datasets representative of the worldwide population receiving radiotherapy treatments. Finally, all tests passed their respective acceptance criteria, thus showing ART-Plan + v3.1.0 clinical acceptability.

Regarding performance on US data:

Our approach is to always include a portion of US data within the testing data every time we wanted to clear a new module/function of the device for the first time in the US: for instance, we did that for Annotate during the first submission then recently for SmartPlan as well, when they were first introduce in the US market. Then, whenever we added new organs/structures or improved our cleared models validated on US data, we did not retest on US data particularly. Moreover, TheraPanacea is planning to expand its product approval in some other region of the world who might also request testing on their population. At some point we would be unable to include all covered regions' population data at 50% in our testing dataset.

However, we have tried as much as possible to collect US data, and the testing dataset is now represented by **31% of US data (Total of 2040 patients for ART-Plan with 1413 EU patients and 627 US patients)**. The table below shows the details of the datasets for Annotate, SmartPlan and AdaptBox.

- Module Annotate: Total of 1844 patients composed of 1254 EU patients and 590 US patients
- Module SmartPlan: Total of 35 patients composed of 25 EU patients and 10 US patients
- Module AdaptBox: Total of 161 patients composed of 134 EU patients and 27 US patients

Clinical tests :Not applicable

Based on the information presented in these 510(k) premarket notifications the TheraPanacea ART-Plan is considered substantially equivalent. The TheraPanacea ART-Plan + 3.1.0 is as safe and effective as the currently marketed predicate device.

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 + 3.1.0 performs within its design specifications and is substantially equivalent to the predicate device.