April 28, 2022

Planmed Oy
℅ Niina Vuorikallas
Quality and Regulatory Director
Sorvaajankatu 7
Helsinki, Helsinki 00880
FINLAND

Re: K213278
Trade/Device Name: Planmed Verity
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS, JAK
Dated: September 27, 2021
Received: October 1, 2021

Dear Niina Vuorikallas:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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)*
K213278

Device Name
Planmed Verity

Indications for Use *(Describe)*

Planmed Verity is intended to be used for X-ray computed cone beam tomography imaging of anatomies within upper and lower extremities, head and neck.

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.

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510(k) Summary

I. SUBMITTER

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Contact person : Brett Hines

Date Prepared: April 25, 2022

II. DEVICE

Name of Device:	Planmed Verity
Common or Usual Name:	Cone Beam Computed Tomography (CBCT) x-ray System
Classification Name:	Computed Tomography X-ray System (CT) (21 CFR 892.1750)
Regulatory Class:	II
Product Code:	OAS, JAK

III. PREDICATE DEVICE

Planmed Verity cone beam computed tomography X-ray System, #K180918. Planmed Verity is classified as computed tomography x-ray system (CT device, 21 CFR 892.1750), class II device with product code OAS or JAK.
This predicate device has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Planmed Verity is a cone beam computed tomography x-ray system for generating 3D imaging scans of extremity, head and neck anatomies. The Planmed Verity utilizes an amorphous silicon based digital image receptor to capture digital images. The toroidal shaped gantry includes a rotating x-ray source combined with a flat panel image receptor. The scan rotation angle is less than a full circle and during the scan 300 to 400 projection images are being acquired. The receptor directly converts the incoming X-ray photons to digital image data. Projection image data is used to generate a 3D image volume of the anatomy through a reconstruction software algorithm.

The workflow with Planmed Verity is controlled from the integrated acquisition workstation and Planmed Verity Manager image acquisition and communications software. The patient information is entered manually or received from the hospital, radiology, or x-ray modality information systems (HIS, RIS, or MIS, respectively), as a format of modality worklist. Subsequently, the images are acquired, processed, and displayed for preview. After initial evaluation by the opeartor, the images are either printed or transferred for soft-copy review.

V. INDICATIONS FOR USE

The Planmed Verity CBCT unit acquires digital 3D X-ray images. The Indications for Use (IFU) statement is as follows:
'The Planmed Verity system is intended to be used for x-ray computed cone beam tomography imaging of anatomies within upper and lower extremities, head and neck.'

The IFU statements are the same for both predicate (currently cleared system version) and subject systems.

Intended use of the Verity system includes pediatric use. The labeling of the device includes instructions for safe imaging of child patients. The User's Manual has guidance for using the reduced field of view collimation for small anatomies and for achieving sufficient image quality for diagnosis together with as low as reasonably achievable dose. During development of the system FDA guideline for pediatric use has been followed: 'Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff'.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

General

Both devices are using the same basic operating principles and are technically almost identical. The user interface is a computer touch screen. The integrated PC is the same for both systems. Operating system is Windows 10 for both systems. X-ray generation and control are the same. The amorphous silicon detector is the same Varex type 2520DX. The Verity Manager software includes image enhancement options like Ultra Low Dose and CALM motion blur canceling protocols. However some new software features have been added to the subject system compared to the predicate device.
A newly added stitching feature has the possibility to combine 2 or 3 volumes of anatomy for the diagnosis of larger views of hand or foot studies. Another added feature is extended field of view volume eFoV imaging which reconstructs parts of a larger volume outside the main FoV volume through calculating sparse data. The eFoV area is marked in the image. The new version of the system may also combine larger anatomies through stitching of two or three volumes into one 3D image.
Some newly developed patient supporting trays include adjustment features to guide the imaging stitching protocol. The eFoV area is marked on the patient support.
The labelling of the system has been updated with the new features, please see section 13. of this submission. The eFoV workflow is explained in detail in the Verity User's Manual in chapter 13.6. The stitching of 2 or even 3 volumes of anatomy is explained in chapter 14.1. of the new Verity User's Manual. New optional patient positioning supports are shown in chapter 8.5 of the Verity User's Manual.

Integrated detector

Quality assurance with pixel defect acceptance criteria comparison is unchanged. Pixel matrixes are identical, pixel width 127 µm vs. 127µm and ADC bit depth is 16 bit for subject and predicate systems.

X-ray unit

Dimensions of the units are the same.

X-ray tube

Units use the same X-ray tube.

X-ray generator

Units use the same X-ray generator.

X-ray collimator

Collimator mechanics functionality and filtration are unchanged.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Planmed Verity CBCT device has been previously tested for acute and repeated toxicity. None of the materials of the device construction have been changed and no new materials have been added to the subject system. Some new optional patient supporting trays have been added to the system and these are being manufactured from same materials like the existing trays. As conclusion, no new materials testing was found necessary. There is no risk or concern to the patient's safety from contact with the materials of construction of this X-ray unit.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing of the system has been previously carried out to show compliance with the recognized standards IEC 60601-1, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-28, IEC 60601-2-54, ISO 10993-1 for safety, and IEC 60601-1-2 for EMC. The subject system has not been changed electrically or mechanically. The newly added features do not require re-testing in the sense of these standards.

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 "Moderate" level of concern.

During the software design process for the device, cybersecurity threats and vulnerabilities have been addressed according to FDA guideline 'Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff' .

Physical laboratory testing

The performance of the system has not changed from the predicate device. The x-ray tube assembly, beam quality and flat field imaging detector are unchanged and the imaging reconstruction software algorithms are the same. Thus no new physical laboratory testing was deemed necessary.

Clinical image evaluation

The newly added software features eFoV, improved CALM motion blur reduction, MAR improved metal artefact removal and stitching algorithm performance have been clinically evaluated. Two experienced radiologists have studied independently a number of sample scans

and diagnostic images to score different essential image quality related items. The results have been summarized in a clinical study report.

The overall image quality was acceptable for all cases and image types. The clinical image quality of the eFoV feature outside the primary field of view is of lower image quality and offers visualization aid, not diagnostic value. This has been acknowledged in device labeling materials.

VIII. CONCLUSIONS

The safe use, imaging performance and usability of the device has been demonstrated for the predicate device. The subject device has not been modified in any way in the sense of electrical safety or imaging performance. Nor has the system's usability been altered.

Because the Planmed Verity system may also be used for pediatric patients the labeling also includes guidance for child imaging. Special care for dose reduction and limitation of the field of view and x-ray field size have been implemented. Guidance for achieving sufficient image quality for diagnosis together with as low as reasonably achievable dose has been given in the labeling.

Software verification and validation demonstrate that the Planmed Verity system performs as intended in the specified use conditions.

The clinical image evaluation study shows that the device performs comparably to the predicate device for the same intended use and that the new software features have acceptable image quality.