November 30, 2018

Planmed Oy
Lars Moring
Regulatory Affairs Manager
Sorvaajankatu 7
HELSINKI, 00880
FINLAND

Re: K180918
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: April 5, 2018
Received: April 9, 2018

Dear Lars Moring:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K180918

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.

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

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510(k) Summary

K180918

I. SUBMITTER

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Contact person : Ed McDonough

Date Prepared: November 28, 2018

II. DEVICE

Name of Device:	Planmed Verity
Common or Usual Name:	Cone Beam Computed Tomography (CBCT) 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, K143435.
This predicate 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 receptor directly converts the incoming X-ray photons to digital image data.

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 operator, the images are either printed or transferred for soft-copy review.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF INDICATIONS FOR USE

An added imaging protocol has been introduced to the system compared with the predicative device version.

The Indications for Use (IFU) statements are similar for both systems. IFU of the predicate system refers to the currently cleared system version with the indications for use covering extremities and head anatomies (mainly maxillofacial and sinus). The new version of the system may also be used for imaging of other head anatomies and the neck. This protocol uses a new patient support tray.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

General
Both the predicate device and the subject device are using the same basic operating principles and are technically almost identical. The subject device is an improved version of the predicate device. It has the same outer design and no changes to the physical construction visible from the outside with the exception of one added optional patient support tray. X-ray generation and control are the same. The controlling PC workstation of the subject device is integrated into the x-ray device like in the predicate system. The user interface is still the same touch screen like in the predicate device and the managing software is essentially unchanged in its controls and functionality and from the operator's perspective. All labeling material is mainly unchanged. Only the added software features are updated to the user's manual and to the technical manual.

Integrated detector
The system uses an integrated flat panel detector. The type of the detector has changed slightly to a new version of the same detector. Pixel matrixes are identical, pixel size is 127 µm by 127µm. Quality assurance with pixel defect acceptance criteria comparison is unchanged.

X-ray unit
Physical dimensions of the units are the same.

X-ray field size and SID
X-ray field size, SID, cone beam geometry and scanning angle are unchanged.

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 has been simplified with same functionality and filtration.

Differences and added features
The complete list of differences of the subject device to the predicate device is as follows:

The integrated PC's brand has been changed from HP to Dell. The Microsoft Windows operating system has been upgraded from Windows 7 to Windows 10.

The Verity Manager software newly includes image enhancement options like ULD (Ultra Low Dose) noise filtration and CALM (Correction Algorithm for Latent Movement) motion blur reduction protocols.

One optional patient supporting tray has been added for the newly introduced head and neck imaging protocols. All previously used patient support options of the predicate system are available and supported also with the subject system.

The amorphous silicon detector is replaced by a new version of the same detector type. The new version of the detector has slightly better imaging characteristics (MTF, DQE and noise performance) as the predicate device. Yet its physical construction, specifications and software interfacing are essentially the same as before.

There are no other differences of the subject system to the predicate system.

The above listed differences are deemed to be non-critical for the subject device compared to the predicate since the system is mainly unchanged. The safety of the system and the imaging performance for the intended use are maintained or improved for the new system version in comparison to the predicate. The added features have been clinically tested and approved by experienced operators and radiologists and found valuable for diagnostic use without adding risks to patient or operator safety or health. Labeling material has been updated to include the new functionality. Dosimetry information has been added to aid in judgement of the radiation safety of intended diagnostic procedures.

VIII. PERFORMANCE DATA

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

Biocompatibility testing

To evaluate biocompatibility of the Planmed Verity CBCT device, we performed safety evaluation of acute and repeat toxicity. As conclusion, none of the compounds measured in the extracts were present at levels which could adversely affect the patient. Thus, 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 were conducted on the Planmed Verity CBCT system. The system complies with 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.

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.

Physical laboratory testing

The performance of the system has not changed from the predicate device. Image quality is not affected by the change of the detector type from 2520D to 2520 DX version. Thus no new physical laboratory testing was deemed necessary. Instead a comparison of the manufacturer's (Varex) non-clinical physics data was performed. Both systems use the same software algorithms and interfacing software to control the flat panel detector and to compute the reconstruction. The image acquisition chain or the imaging protocols' number of frames and scan angles have not been altered in the subject system compared to the predicate device.

Clinical image evaluation

A clinical image evaluation has been performed where an experienced radiologist scored representative sample scans and diagnostic images. The overall image quality was acceptable for all cases and image types.

Parts of the clinical evaluations were performed with a system not being in final finished form of the subject device. More precisely the flat panel detector used has been of type 'D' not 'DX'. However since the imaging performance of both types is essentially equal and would not alter the scoring of the image quality seen by the radiologist we believe that all clinical testing is relevant and acceptable for the verification of the subject device.

It may also be noted that the new software features CALM and ULD can be upgraded to the predicate Verity systems. Once cleared for marketing, these features will benefit also the currently installed base of units and the patient diagnostics and radiation safety.

IX. CONCLUSIONS

The renewed UL/CB/CE testing and certification process support the safe use and imaging performance and usability of the device. Both hardware and software verification and validation demonstrate that the Planmed Verity system performs as intended in the specified use conditions. The clinical image evaluation also shows that the device performance is equal to the predicate device that is currently marketed for the same intended use. The added software features CALM and ULD improve image quality and lower the patient dose while maintaining and/or improving diagnostic image quality.

Summary of conclusions drawn from the clinical and non-clinical testing:

Since the overall construction, x-ray generation or control software have not changed significantly there are no new added risks to the subject device. The integrated flat panel detector has changed to a newer version with the same imaging performance specifications. Hence no new physical laboratory testing was deemed necessary. Only the new revision of the flat panel imaging detector performance has been compared for its non-clinical testing data and was found equal or slightly better.

The clinical tests included imaging performance scoring with use of the CALM motion blur reduction software feature, as well as use of the ULD ultra low dose imaging protocol for patient radiation dose reduction.

The clinical test report describes the CALM feature in detail. The scoring using CALM compared to not using it is presented. Based on this evaluation the CALM feature improves the imaging quality in most cases and hence it reduces the risk of re-takes because of patient movement. An added section with results of imaging performance evaluation with CALM is presented.
The effectiveness of the CALM feature was additionally verified with imaging a scull phantom with suitable test inserts. Simulated small and large amplitude motion blur as well as step-like distortion was added to the projection images and the effectiveness of the CALM feature to correct the motion blur was verified. Results show that the CALM algorithm clearly reduces motion blur.

ULD protocol was verified in a separate study at a clinic in Helsinki, Finland. The radiologists evaluated the clinical image quality of the ULD feature to be clinically suitable for imaging head and neck anatomies.

Based on the clinical tests performed it can be concluded that the subject device is as safe and effective for its indicated use as the predicate system when used as instructed.