DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

May 14, 2015

Re: K143435
Trade/Device Name: Planmed Verity
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS, JAK
Dated: April 24, 2015
Received: April 29, 2015

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143435

Device Name
Planmed Verity

Indications for Use *(Describe)*
Planmed Verity is intended to be used for X-ray computed tomography imaging of anatomies within upper and lower extremities and maxillofacial area.

The device is to be operated and used by legally qualified health care professionals.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

DATE
April 24th, 2015

PRODUCT, CLASSIFICATION NAME
Trade Name: Planmed Verity
Common Name: Computed Tomography X-ray System
Classification Name: Computed Tomography X-ray System
Product codes: OAS (primary), JAK (secondary)
Class: II
Regulation: 21 CFR 892.1750

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Contact person: Bob Pienkowski

INTENDED USE
Planmed Verity is intended to be used for X-ray computed tomography imaging of anatomies within upper and lower extremities and maxillofacial area.

The device is to be operated and used by legally qualified health care professionals.

PRODUCT DESCRIPTION
Planmed Verity utilizes the CBCT (Cone Beam Computed Tomography) technology with a flat panel detector to provide high resolution volumetric images. During image acquisition the detector and X-ray tube perform a single rotation around the target of imaging, during which an amount of snapshot X-ray images are acquired. The X-ray radiation is pulsed so that it is active only when data is collected for the projection images. Before reconstruction, calibration corrections are applied to the image data. The reconstruction is then performed using a dedicated reconstruction engine and algorithm.

The system is designed as a compact, stand-alone unit from which the whole imaging procedure from patient information management to image acquisition, processing and archiving can be performed.
The unit provides a motorized gantry with adjustable height and tilt for the best possible extremity and maxillofacial area positioning. The construction also enables a weight-bearing option, in which the patient stands inside the gantry during image acquisition. Weight-bearing imaging of the extremity shows the anatomy under natural load.

PREDICATE DEVICE
We consider this product to be similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

510(k) # K061834 Xoran xCAT™

SUBSTANTIAL EQUIVALENCE
The intended use of Planmed Verity and the predicate device is similar. Planmed Verity is intended to be used for imaging anatomies within upper and lower extremities and maxillofacial area. Intended use of the predicate device covers these same areas. Planmed Verity and the predicate device both utilize cone beam computed tomography technology with substantially equivalent technical characteristics for acquiring 3D image data sets of these anatomical areas.

Non-clinical physical laboratory testing studies were completed for the product to compare the imaging performance of Planmed Verity and the predicate device. This testing included a wide range of different physical evaluations for performance, image quality and dose levels. All results were equivalent or slightly better in Planmed Verity than in the predicate device.

A clinical study was completed to evaluate the image quality of Planmed Verity's maxillofacial area. The images for this clinical study were selected from patients imaged as part of normal clinical routine in a university hospital in Finland. The results show that the imaging position, which is different from the one in the predicate device, gives a clinically sufficient image quality.

The safety of selected patient positioning has been analyzed as a part of the risk analysis. As an outcome it is concluded that the selected design methods ensure that the selected patient positioning for head area imaging is safe when used as labeled. The sitting position and open design of Planmed Verity makes it also easy for the patient to move away from the device whenever needed.

CONCLUSIONS
The intended use and technical characteristics are basically the same for both compared devices. The most evident difference is the patient positioning, which has, however, no notable effects on achieved imaging performance characteristics. Both devices are safe when used as labelled.

Based on the non-clinical and clinical studies the imaging performance of Planmed Verity was found both substantially equivalent to the predicate device and sufficient for clinical use.

The comparison demonstrates that Planmed Verity is as safe and effective as the predicate device.