Planmed Oy
% Mr. Lars Moring
Regulatory Affairs Manager
Sorvaajankatu 7,
FI-00880, Helsinki
FINLAND

December 28, 2017

Re: K163328
Trade/Device Name: Planmed Clarity
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: November 21, 2017
Received: November 27, 2017

Dear Mr. 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.

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.

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,

Michael D. O'Hara For

Robert 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)*
K163328

Device Name

Planmed Clarity

Indications for Use *(Describe)*

The Planmed Clarity 2D mammography unit acquires digital 2D mammographic images. The Planmed Clarity 2D system is intended to be used for screening and diagnosis of breast cancer. The Planmed Clarity system may also be used for additional diagnostic workup of the breast.

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

I. SUBMITTER

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Contact person : Brett Hines

Date Prepared: October 24, 2017

II. DEVICE

Name of Device:	Planmed Clarity
Common or Usual Name:	Full Field Digital Mammography (FFDM) System
Classification Name:	Full Field Digital Mammography (FFDM) System (21 CFR 892.1715)
Regulatory Class:	II
Product Code:	MUE

III. PREDICATE DEVICE

Planmed Nuance Excel Full Field Digital Mammography System, K111361
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Planmed Clarity is a Full Field Digital Mammography (FFDM) system for generating mammographic images that can be used for screening and diagnosis of breast cancer. The Planmed Clarity 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 Clarity is controlled from the acquisition workstation and Planmed Clarity Manager image acquisition and communications software. The patient information is entered manually or received from the hospital, radiology, or mammography 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 user, the images are either printed or transferred for soft-copy review.

V. INDICATIONS FOR USE

The Planmed Clarity 2D mammography unit acquires digital 2D mammographic images. The Planmed Clarity 2D system is intended to be used for screening and diagnosis of breast cancer. The Planmed Clarity system may also be used for additional diagnostic workup of the breast.

The Indications for Use (IFU) statement are similar for both systems. IFU of the predicate system refers to film-screen mammography, a technology which has been later replaced by digital systems. This difference in wording has no effect on the indications for use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

General
Both devices are using the same basic operating principles and are technically very similar. The user interface has been changed to dual touch-screens. X-ray generation and control are the same. The compression unit and AEC technology are the same. The active material has been changed to amorphous silicon, but otherwise the new detector has almost identical imaging characteristics and signal processing as the predicate device.

Integrated detector
Quality assurance with pixel defect acceptance criteria comparison is similar. Pixel matrixes are identical, pixel width 83 µm vs. 85µm and ADC bit depth 14 vs. 13 bit for subject vs. predicate system, respectively.

X-ray unit
Dimensions of the units are similar.

X-ray tube
Units use the same X-ray tube.

X-ray generator
Units use the same X-ray generator.

X-ray anti-scatter grid
Same grid is used on both systems.

VII. PERFORMANCE DATA

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

Biocompatibility testing
To evaluate biocompatibility of the Planmed Clarity full field digital mammography 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 mammography unit.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the Planmed Clarity mammography system. The system complies with IEC 60601-1, IEC 60601-1-6, IEC 60601-2-28, IEC 60601-2-45, 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 was tested according to Class II Special Controls Guidance Document: Full-Field Digital Mammography System Document issued on: March 27, 2012.

Summary of physically laboratory testing results:

1. Sensitometric response: Both detectors respond linearly to radiation exposure
2. Spatial resolution: The predicate system has on average 10% higher MTF at 5 lp/mm. Difference is likely due to direct signal conversion of the a-Se detector.
3. Noise analysis: The subject device is less sensitive to noise at higher frequencies. At lower doses, the difference becomes more pronounced. Also SNR and CNR are higher.
4. Dynamic range: The subject device produces higher DQE than the predicate system
5. Repeated exposures: Ghost tolerance was similar.
6. Automatic Exposure Control (AEC) performance: With automatic filtration change the organ and entrance doses are below EUREF reference values.
7. Phantom test: RMI phantom scores for all attributes are higher for the subject device. CDMAM test pass for both systems.
8. Patient radiation dose: Both systems achieve lower patient radiation dose than the EUREF reference level.
9. Breast compression system: Powered compression pressure test results are similar.

Clinical image evaluation

We also performed clinical image evaluation where MQSA certified experienced radiologist scored representative sample mammograms and diagnostic images. The overall image quality was acceptable for all cases and image types.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the Planmed Clarity full field digital mammography system should perform as intended in the specified use conditions. The clinical image evaluation also shows that the device performs comparably to the predicate device that is currently marketed for the same intended use.