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

October 23, 2020

Re: K192317
Trade/Device Name: Planmed Clarity 2D and Clarity S
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: September 22, 2020
Received: September 25, 2020

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/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,

For

Thalia T. Mills, Ph.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192317

Device Name

Planmed Clarity 2D and Clarity S

Indications for Use *(Describe)*

The Planmed Clarity 2D and Planmed Clarity S mammography units acquire digital 2D mammographic images. The Planmed Clarity 2D/S systems are intended to be used for screening and diagnosis of breast cancer. The Clarity 2D/S systems 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.

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510(k) Summary

(updated version 3.)
K192317

I. SUBMITTER

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Date Prepared: October 23, 2020

II. DEVICE

Name of Device:	Planmed Clarity 2D and Clarity S
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 Clarity Full Field Digital Mammography X-ray System, **K163328**
This predicate system has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Planmed Clarity **2D** and Clarity **S** are Full Field Digital Mammography (FFDM) systems for generating mammographic x-ray images that can be used for screening and diagnosis of breast cancer. Planmed Clarity **2D** and Clarity **S** utilize an amorphous silicon based digital image receptor to capture images. The receptor directly converts the incoming X-ray photons to digital image data.

The workflow with Clarity **2D** is controlled by the side displays/touch panels and the workflow of Clarity **S** is controlled from the acquisition workstation and Clarity Manager 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 and S mammography units acquire digital 2D mammographic images. Both systems are intended to be used for screening and diagnosis of breast cancer. The Clarity 2D and S systems may also be used for additional diagnostic workup of the breast.

The Indications for Use (IFU) statement are the same for both subject and predicate systems.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

General
Both predicate and subject devices are using the same basic operating principles and are technically very similar. The Clarity 2D system is similar to the predicate Clarity. The 2D system can be technically upgraded to a DBT system in the field (not for the US market). The Clarity S system is a value system derived from Clarity and it cannot be upgraded to DBT. The dual touch-screen user interfaces of Clarity and Clarity 2D are omitted from Clarity S. X-ray generation and control are identical in both systems. The compression system and AEC technology are the same.

Integrated detector
The digital full field flat panel detector is a new version of the Clarity detector. The new detector has essentially identical imaging characteristics and signal processing as the predicate device. Quality assurance with pixel defect acceptance criteria comparison is similar. Pixel matrixes are identical, pixel width 83 µm. ADC bit depth is 16 bit for the subject system vs. 14 bit for the predicate system. Software interface to communicate with the detector has not been changed.

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.

Software
The Clarity Manager workstation software was changed to run on Windows 10 instead of Windows 7 of the predicate system. The software of the system has been improved to include encrypted DICOM communication. Imaging sequence has been made shorter by improving the software interface with the detector and with some optimization of the x-ray generator timing. The software has been adapted for the higher dynamic range of the new detector version (from 14 bit to 16 bit). Also some new hardware version related changes of the user interfaces have been made. A detailed software description document is included with this submission along with a comprehensive description of changes between software versions of the predicate device to the subject device.

Risks
Cyber security risks and their mitigations have been addressed more closely and comprehensively with the latest software release for the subject systems. New hazards in comparison to predicate device have been identified and addressed.

Table 1: Comparison of device specifications

Device	**Planmed Clarity 2D**	**Planmed Clarity S**	**Planmed Clarity**
	Subject device	**Subject device**	**Predicate device**
General comparison			
Description	Full Field Digital Mammography system	Full Field Digital Mammography system	Full Field Digital Mammography system
System configuration	X-ray stand and Workstation PC	X-ray stand and Workstation PC	X-ray stand and Workstation PC
Application software	Clarity Manager 2.3 on Windows 10	Clarity Manager 2.3 on Windows 10	Clarity Manager 1.3 on Windows 7
User interfaces	Touch screen user interface side displays on both sides of x-ray stand	No side displays on x-ray stand, user interface included in workstation PC display	Touch screen user interface side displays on both sides of x-ray stand
'Side access' feature for easier patient positioning	yes, standard	not available	yes, standard
Control switches	additional C-arm control switches, compression fine adjustment	no additional switches	additional C-arm control switches, compression fine adjustment
Upgradeability	DBT with s2D (not in US)	not upgradeable to 3D	DBT with s2D (not in US)
	stereotactic device (not in US) optional	not upgradeable with stereotactic device	stereotactic device (not in US) optional
Detector comparison			
Detector type	Varex Paxscan 3024MX	Varex Paxscan 3024MX	Varex Paxscan 3024M
Detector technology	Amorphous silicon (a-Si) with CsI:TI scintillator TFT array	Amorphous silicon (a-Si) with CsI:TI scintillator TFT array	Amorphous silicon (a-Si) with CsI:TI scintillator TFT array
Pixel matrix	2816x3584	2816x3584	2816x3584
Size of active area	23.1x29.1cm	23.1x29.1cm	23.1x29.1cm
Pixel size	83 µm	83 µm	83 µm
ADC bit depth	16 bit	16 bit	14 bit
Pixel fill factor	0.52	0.52	0.70
Readout time	236 ms	236 ms	495 ms
(all other imaging effecting specifications are substantially equal for all these systems)			

VII. PERFORMANCE DATA

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

Biocompatibility testing

Since the subject systems are almost identical to the predicate device, no new patient contacting mechanical parts have been added to the subject system. Hence no new biocompatibility testing was necessary. Thus, there is no risk or concern to the patient's safety from contact with the materials of construction of this new 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. The only electrical difference is the flat panel detector type which has been separately emc tested by TÜV Rheinland (please see attached emc testing report in VOL17.)

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 physical laboratory testing (bench testing) results:

1. Sensitometric response: Both detectors respond linearly to radiation exposure
2. Spatial resolution: Both systems perform similar in terms of MTF since the detector scintillator material or thickness are the same and detector element pixel size is the same.
3. Noise analysis: The subject device has slightly better noise performance. Also SNR and CNR are slightly 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 well within generally accepted levels. With a 40 mm PMMA phantom corresponding to an average breast thickness and glandularity, organ dose was measured 1.23 mGy with W/Ag beam quality.
7. Phantom test: RMI phantom scores for all attributes are similar for subject and predicate devices. CDMAM test passes with both systems.
8. Patient radiation dose: With varying phantom thickness and varying adiposity and glandularity factors, both systems achieve radiation dose levels well within generally acceptable limits.
9. Breast compression system: Powered compression pressure test results are similar.

Clinical image evaluation

Clinical image evaluation was performed with the subject Clarity 2D system. Purpose was to determine if the image quality were judged to be of sufficiently acceptable quality for mammographic usage when reviewed by MQSA qualified experienced radiologists. The images were taken in one site in Bulgaria where 6 patients participated to routine breast cancer screening. Images assigned BI-RADS score 1 or 2 were selected for the evaluation. Some cases also included diagnostic mammograms, i.e. spot and/or magnification images. The images were then reviewed by two MQSA qualified experienced US radiologists independently. All images were rated good or excellent and thus 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 2D and S full field digital mammography systems perform as intended in the specified use conditions. The clinical image evaluation also shows that the devices equipped with the new detector version perform comparably to the predicate device that is currently marketed for the same intended use.