July 18, 2022

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

Re: K211720
Trade/Device Name: Planmed Clarity 2D, Planmed Clarity S
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: June 14, 2022
Received: June 17, 2022

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,

For

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: Office of 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)*
K211720

Device Name

Planmed Clarity 2D, Planmed Clarity S

Indications for Use *(Describe)*

The Planmed Clarity 2D and S mammography units acquire digital 2D mammographic images. The Planmed Clarity 2D and S systems are intended to be used for screening and diagnosis of breast cancer. The Planmed Clarity 2D and S systems may also be used for additional diagnostic workup of the breast. Additionally, the Planmed Clarity 2D and S systems can be used to provide digital x-ray images of breast biopsy specimens.

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 K211720

## I. SUBMITTER

**Manufacturer**
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Contact person : Brett Hines

Date Prepared: July 18, 2022

## 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, #K192317
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. Additionally, the Planmed Clarity 2D and S systems can be used to provide digital x-ray images of breast biopsy specimens.

The Indications for Use (IFU) are the same for both subject and predicate systems, but the wording has been clarified for the subject device submission.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

**General**

Both predicate and subject devices are using the same operating principles and are technically similar. In fact the subject systems 2D and S have not been changed in design, construction or features from the predicate. The 2D system can be technically upgraded to a 3D DBT system in the field (not for the US market). The Clarity S system is a value system derived from Clarity 2D and it cannot be upgraded to DBT. The dual touch-screen user interfaces of 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. Main specifications of both systems can be found in Table 1. below.

This application is mainly describing a software change to the image processing algorithm. Since processing of the raw images acquired directly with a digital x-ray flat panel detector by a software algorithm is crucial for diagnostic performance for a mammographic system, changing from one algorithm to another requires full software verification testing and clinical performance evaluation for the intended use.

**Integrated detector**

Clarity 2D and S are using a digital full field flat panel detector. Detector type and model are the same for both the subject and predicate devices. Software interface to communicate with the detector has not been changed. Imaging characteristics and signal processing are similar for both predicate and subject devices. Image processing software algorithm for the acquisition workstation however has been changed. Quality assurance with pixel defect acceptance criteria comparison is unchanged.

**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 anti-scatter grid**

Same grid is used on both systems.

**Software**

The Clarity Manager workstation software is running on Windows 10. While there are incremental improvements in the software for stability and smaller bug fixes the main improvement is the newly developed image processing algorithm entitled CORE. It is developed by Planmed in-house and replaces the legacy third party licensed software.

The new Clarity manager software version also supports RDSR (radiation dose structured report) for DICOM.

A detailed software description documentation is included with this submission along with a comprehensive description of changes between software versions of the predicate device to the subject device. The new image processing algorithm is explained in detail in section 16. document

'D0014495-A_CORE_Post-Processing_Software_Design_Specification.pdf'. Because of other incremental software improvements and bug fixes most of the software documentation has been updated to newer versions. For this reason the updated software documents do replace the previous ones submitted for the previous clearance.

**Risks**

Risk management has been updated to include risks related to the new image processing software CORE. Also other new hazards in comparison to predicate device have been identified and addressed. CORE related risks are analyzed in the end of the RM file, section 16. document 'D0004598-52 Clarity Risk Analysis' . For traceability of hazardous situation, safety control, requirement specification, design specification and verification an application software Polarion has been used. This software provides efficient tools to link above mentioned items. A view of the cross reference matrix is provided in section 16. in document 'D0012009-H Clarity Software Traceability Matrix.pdf'.

**Table 1: Device specifications**

| **Device** | **Planmed Clarity 2D** | **Planmed Clarity S** |
|---|---|---|
| | **Subject device** | **Subject device** |
| **General comparison** | | |
| Description | Full Field Digital Mammography system | Full Field Digital Mammography system |
| System configuration | 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 |
| 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 |
| 'Side access' feature for easier patient positioning | yes, standard | not available |
| Control switches | additional C-arm control switches, compression fine adjustment | no additional switches |
| Upgradeability | DBT with s2D (not in US) | not upgradeable to 3D |
| | stereotactic device (not in US) optional | not upgradeable with stereotactic device |
| | | |
| **Detector comparison** | | |
| Detector type | Varex Paxscan 3024MX | Varex Paxscan 3024MX |
| Detector technology | Amorphous silicon (a-Si) with CsI:Tl scintillator TFT array | Amorphous silicon (a-Si) with CsI:Tl scintillator TFT array |
| Pixel matrix | 2816x3584 | 2816x3584 |
| Size of active area | 23.1x29.1cm | 23.1x29.1cm |
| Pixel size | 83 µm | 83 µm |
| ADC bit depth | 16 bit | 16 bit |
| Pixel fill factor | 0.52 | 0.52 |
| Readout time | 236 ms | 236 ms |

## VII. PERFORMANCE DATA

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

**Biocompatibility testing**
Since the subject systems are identical to the predicate devices and no new patient contacting mechanical parts have been added to the subject system, previously performed biocompatibility testing of Clarity is still valid for both systems Clarity 2D and S. 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 the Clarity 2D and S devices.

**Electrical, mechanical and radiation safety**
Electrical, mechanical and radiation safety testing of subject systems Clarity 2D and S are also still valid because the construction and design is unchanged. The systems have been tested according to the UL/CB scheme by UL Demko in Denmark, including software life cycle process and human factor engineering. The systems comply with: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1-Ed3.1:2012, IEC 60601-1-3-Ed2.1:2013, IEC 60601-2-45-Ed3.1:2015, IEC 62304_Ed1.1:2015, clauses 4.3, 5, 7, 8 and 9, IEC 60601-1-6-Ed3.1:2013, IEC 62366-1_Ed1.0:2015

**Electromagnetic compatibility (EMC)**
Since the latest clearance of Clarity 2D and S (K192317) an update to the emc certificate has been performed according to IEC 60601-1-2-Ed4:2014. The new version of the standard includes among others some more demanding test levels and monitoring of the essential performance during radiated and conducted radio frequency immunity testing. The latest test certificate is attached in section 17. of this application.

**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." Software test planning documents and test reports are provided in section 16. of this application. The software for this device was considered as "Moderate" level of concern.

**Physical laboratory testing**
The currently cleared Clarity 2D and S systems (K192317) were tested according to Class II Special Controls Guidance Document: Full-Field Digital Mammography System Document issued on: March 27, 2012. The predicate systems do not differ in respect to their imaging chain components or software for raw images acquisition. Hence there is no need to repeat the physical laboratory testing for the subject systems with this application. However, image quality phantom studies were conducted on the processed images to evaluate the substantial equivalence between the predicate device and new CORE feature in terms of safety and effectiveness.
The physical laboratory testing for the previous clearance and new information included the following in section 18. 'Performance Testing – Bench' :

Summary of physically laboratory testing results:
1. Sensitometric response, linearity
2. Spatial resolution, MTF (modulation transfer function)
3. Noise analysis, DQE (detective quantum efficiency)
4. Dynamic range
5. Repeated exposures, ghosting and lag performance
6. Automatic Exposure Control (AEC) performance according to EUREF reference values
7. Phantom test: RMI phantom scores, CDMAM contrast detail performance
8. Patient radiation dose according to EUREF reference level
9. Breast compression system

**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 interpreting physicians. Both clinical testing protocol and clinical testing report are very similar with the previously cleared Clarity 2D system. The images were taken at one site in Belgium and one site in Bulgaria where altogether 6 patients participated to routine breast cancer screening. Both sites used Planmed Clarity 2D systems with Varex 3024MX amorphous silicon detectors. Images were processed with the new Planmed CORE software algorithm. 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 three MQSA qualified experienced US interpreting physicians independently. All images were rated good or excellent and thus the overall image quality was acceptable for all cases and image types. The acceptance criteria and scoring tables used are substantially the same as with the previously cleared Clarity system. The clinical testing results can be found in section 20. document 'Summary of 510k CORE clinical studies for Planmed Clarity 2D.pdf'.

**Labeling**

Since the design and functionality or the user interfaces have not been changed with this software update there are no major differences in labeling. The updated EMC certification to the latest version of the IEC60601-1-2-Ed4:2014 standard however has required some updates, added notes and warnings to both user's manuals and technical manuals. Hence the latest versions of labeling is attached in section 13. 'Proposed Labeling'.

## VIII. CONCLUSIONS

The non-clinical data of the detector image quality measurements performed earlier to the system support the safety of the device and the hardware and software verification and validation for the latest version 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 image processing software version perform comparably to the predicate device that is currently marketed for the same intended use.