December 15, 2021

Metaltronica Spa
℅ Rachel Paul
Senior Consultant QA&RA
Emergo Europe Consulting
Prinsessegracht 20
The Hague, 2514AP
NETHERLANDS

Re: K202822
Trade/Device Name: Helianthus
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE
Dated: November 4, 2021
Received: November 5, 2021

Dear Rachel Paul:

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)*
K202822

Device Name
Helianthus

Indications for Use *(Describe)*
Helianthus is intended to produce two dimensional digital mammographic images of the breast for diagnosis of breast cancer. Its intended use is for diagnosis, screening, or for needle localization in case of stereotactic biopsy.

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

Helianthus

1. Submission Sponsor

Metaltronica Spa
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Contact Name: Gloria Pesce Delfino
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3. Date Prepared

10/28/2021

4. Device Identification

Trade/Proprietary Name:	Helianthus
Common/Usual Name:	Full-field digital mammography system
Classification Name:	Full-field digital mammography system
Regulation Number:	892.1715
Product Code:	MUE
Class:	Class 2
Classification Panel:	Radiology

5. Legally Marketed Predicate Device(s)

Device name: Planmed Clarity
510(k) number: K163328

Manufacturer: Planmed Oy

The Planmed Clarity is a mammography X-ray unit system that acquires digital 2D mammographic images. The Planmed Clarity mammography X-ray unit system is intended to be used for screening and diagnosis of breast cancer. It incorporates a stereotactic biopsy device.

6. Indication for Use Statement

Helianthus is intended to produce two-dimensional digital mammographic images of the breast for diagnosis of breast cancer. Its intended use is for diagnosis, screening, or for needle localization in case of stereotactic biopsy.

7. Device Description

Helianthus is a mammography solution composed of equipment and software for different examination types and optimized for digital imaging.

Helianthus is a digital mammography system also called full-field digital mammography (FFDM) system. It is an integrated system that includes both the X-ray delivery system and integrated detector. It consists of an x-ray generator, x-ray control, x-ray tube, collimator, beam filter, breast compression system, grid, image receptor system, and accessories. The image receptor system consists of a built-in full-filed solid state detector, acquisition software, acquisition work station (AWS), and accessories. It includes an optional stereotactic biopsy device (BYM 3D DMD) with its respective Operator's Manual.

Helianthus is intended to produce two-dimensional digital mammographic images of the breast for diagnosis of breast cancer. Its intended use is for diagnosis, screening, or for needle localization in case of stereotactic biopsy

8. Substantial Equivalence Discussion

The following table compares the Helianthus to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Attribute	**Helianthus**	**Planmed Clarity/Planmed Oy**	**Comparison**
510(k) Number	N/A	K163328	N/A
Product Code	MUE	MUE	Same
Regulation Number	892.1715	892.1715	Same
Intended Use	Helianthus is intended to produce two-	The mammography X-ray unit system acquires	Same; while the Indications for Use are

Attribute	Helianthus	Planmed Clarity/Planmed Oy	Comparison
	dimensional digital mammographic images of the breast for diagnosis of breast cancer. Its intended use is for diagnosis, screening, or for needle localization in case of stereotactic biopsy.	digital 2D mammographic images. The mammography X-ray unit system is intended to be used for screening and diagnosis of breast cancer.	stated somewhat differently, both devices acquire digital 2D mammographic images and intended to be used for screening and diagnosis of breast cancer. Both include a stereotactic biopsy device.
Presentation	FFDM system composed of a mammography unit, C-arm, acquisition work station and stereotactic biopsy device	FFDM system composed of a mammography unit, C-arm, acquisition work station and stereotactic biopsy device	Same
Electrical Power	For 115/220/230/240 Vac: Momentary: 85/45/43/41 A Long-time: 2.5/1.3/1.2/1.2 A	250VA, 4500VA max. 5 seconds	Similar; higher characteritics. Raises no new questions of safety and effectiveness.
Generator Type	High frequency	High frequency	Same
X-ray Tube	XM1016T XK1016T M113T	M113T	Similar; X-ray tubes XM1016T and XK1016T have similar characteristics than M113T tube. Raises no new questions of safety and effectiveness.
Detector	Amorphous Selenium	TFT/PIN Photodiode amorphous silicon FPD	Similar; the physical laboratory testing results show the equivalence in terms of performance. No impact on safety.

Attribute	Helianthus	Planmed Clarity/Planmed Oy	Comparison
Breast Compression System – Maximum compression that can be applied (N)	200	200	Different; Helianthus complies with IEC60601-2-45 (for power driven compression limited to 200N).
Radiation Shield – Radiation Protection Screen (w x h x d (cm)) and Lead Equivalence of the Protection Screen (mm Pb)	70 x 200 integrated in optional remote AWS Or 70x210 optional (in case of local AWS) 0.34 (0.5 optional)	77.5 x 188 0.3 (0.5)	Similar. Raises no new questions of safety and effectiveness.
Stereotactic Biopsy Device	Complies with IEC 60601-2-45	Complies with IEC 60601-2-45	Same
DICOM	DICOM Services, SCU, Storage Commitment, MPPS, worklist management SCU, structured report, media storage, print	DICOM Services, SCU, Storage Commitment, MPPS, worklist management SCU, structured report, media storage, print	Same
Complies with ISO 10993-1	Yes	Yes	Same
Electrical Safety Testing Passed	Yes	Yes	Same

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Helianthus and to show substantial equivalence to the predicate device, Metaltronica Spa completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The Helianthus passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Cytotoxicity testing of breast support material per ISO 10993-5 - Passed
- Irritation testing of breast support material per ISO 10993-5 – Passed
- Sensitization testing of breast support material per ISO 10993-10 – Passed
- Chemical characterization of compression paddles – Demonstrated chemical stability
- Cytotoxicity testing of compression paddles part per ISO 10993-5 - Passed
- Irritation testing of compression paddles part per ISO 10993-5 – Passed
- Sensitization testing of compression paddles part per ISO 10993-10 – Passed
- Electrical safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 – Passed
- Photobiological safety of lamps and lamp systems testing per IEC 62471 – Passed
- Software verification and validation per IEC 62304/FDA Guidance – software system met its specification and fulfilled its purpose
- Assessment of the imaging characteristics of the Helianthus system through physical laboratory testing (sensitometric response, spatial resolution, noise analysis, signal-to-noise transfer – DQE, dynamic range, image erasure and fading, repeated exposure test, automatic exposure control performance, phantom testing, patient radiation dose, breast compression system) as required by the Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full-Field Digital Mammography System issued on April 4, 2012 (Section 8 Physical Laboratory Testing) - the Helianthus performed as intended and was established to be substantially equivalent in terms of safety and effectiveness to the predicate device.
- Positioning accuracy of the biopsy needle of the Stereotactic Biopsy Device per IEC 60601-2-45 - Passed
- Vibrations testing per EN 60721-3-2 and environmental tests (shock and fall testing) on an mammography unit and accessories when in the crate - Demonstrated package integrity maintained
- Vibrations and shock testing per ISTA 1A of the AWS Monitor - Demonstrated package integrity maintained
- Mechanical and environmental testing and rudimentary transportation case testing per EN 60721-3-2 of the detectors - Demonstrated package integrity maintained

10. Clinical Performance Data

A clinical image evaluation as required by the Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full-Field Digital Mammography System issued on April 4, 2012 (Section 9 Clinical Image Evaluation) was conducted with the Helianthus and determined that the images, reviewed by expert radiologists, were of sufficiently acceptable quality for mammographic usage and that the images are substantially equivalent to those from a predicate device.

11. Statement of Substantial Equivalence

Helianthus has the same intended use as the Planmed Clarity. Any minor differences in the technological characteristics of the subject device when compared to the predicate device have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, Helianthus has been determined to be substantially equivalent to Planmed Clarity.