Olea Medical
% John J. Smith, M.D, J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
WASHINGTON DC 20004

August 2, 2021

Re: K211431
Trade/Device Name: breastscape v1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: May 7, 2021
Received: May 7, 2021

Dear Dr. Smith:

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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*
K211431

Device Name

breastscape V1.0

breastscape V1.0 is an optional image processing software application that is intended for use on Olea Sphere 3.0 software package. It is intended to be used by trained breast imaging physicians and trained MRI technologists.

breastscape V1.0 includes a software module (BreastApp) that supports the visualization, analysis, and reporting of lesions measurements and analysis. breastscape V1.0 supports the evaluation of dynamic MR data acquired during contrast administration and the calculation of parameters related to the uptake characteristics.

breastscape V1.0 performs other user selected processing functions (such as image subtraction, multiplanar and oblique reformats, 3D renderings).

The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image.

breastscape V1.0 can also be used to provide measurements of the segmented tissue volumes (volumes of interest) based on uptake characteristics. These measurements include volume measurement, distances of volumes of interest to anatomical landmarks, 3D longest diameter and 2D long and short axis.

breastscape V1.0 includes the option to add annotations based on the fifth edition of the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS®) Breast Imaging Atlas.

breastscape V1.0 may be used as an image viewer of multi-modality digital images, including ultrasound and mammography. breastscape V1.0 is not intended for primary interpretation of digital mammography images.

breastscape V1.0 includes a software module (BreastLoc) to assists users in planning MR guided breast interventional procedures. Using information from MR images, regarding user-specified target lesion and fiducial location coordinates, the software gives calculation of the targeted region of interest (such as suspected lesion) depth.

When interpreted by a skilled physician, breastscape V1.0 provides information that may be used for screening, diagnosis, and interventional planning.

Patient management decisions should not be based solely on the results of breastscape V1.0.

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

Olea Medical's breastscape V1.0

K211431

Submitter

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Date Prepared: August 2, 2021

Name of Device: breastscape V1.0

Common or Usual Name: PACS

Classification Name: Medical Image Management and Processing System

Regulatory Class: 21 CFR 892.2050

Product Code: QIH, LLZ

Predicate Device

MultiView V4.0.3.2,

- Manufacturer: Hologic, Inc. (K132316)
- Device Name: MultiView V4.0.3.2
- Regulation Number: 21 CFR 892.2050
- Product Code: LLZ

Reference Device

for Kinetics: Olea Sphere V3.0 (K152602)

- Manufacturer: Olea Medical
- Device Name: Olea Sphere V3.0
- Regulation Number: 21 CFR 892.2050
- Product Code: LLZ

Device Description

breastscape V1.0 is an optional PACS software tool that is intended for use with the Olea Sphere V3.0 software package, cleared under K152602. The software accesses image series in DICOM format through Olea Sphere V3.0, which is a software package used to perform image viewing, processing and analysis of medical images.

breastscape V1.0 is made of two software modules: BreastApp and BreastLoc.

1. BreastApp

BreastApp is designed to assist in the visualization, analysis and reporting of Magnetic Resonance Imaging (MRI) breast studies. This module supports the evaluation of dynamic MR breast data acquired during contrast administration (DCE-MRI), and the calculation of parameters related to the lesion uptake characteristics. This module provides semi-automatic segmentation of volumes of interest, distance measurements and lesion volume measurements.

BreastApp provides the features below:

- Visualization of registered MR image series. It includes well-established tools dedicated to standard image viewing, MIPs, reformats and 3D volume rendering.

- Visualization of Mammography and Ultrasound image series for display purpose only.

- Evaluation of dynamic MR breast data acquired during contrast administration. It includes:

    - The computation of image subtractions (subtractions of each time point/phase image of the dynamic series with the 1st time point (baseline) image to highlight tissue with contrast enhancement).

    - The display of time intensity signal curves (kinetics curves) showing tissue contrast enhancement evolution over time.

    - The detection and display of the kinetics curve showing the worst kinetics behavior (most important washout among pixels having peak enhancement superior at 50% enhancing threshold).

    - The computation of semi-quantitative kinetics maps that are derived from the time intensity signal curves and showing uptake characteristics (e.g., Time to Maximum contrast Enhancement, Wash in, Washout, etc.).

- Automatic detection of breast morphological structures. It includes the automatic detection of nipple position, chest and skin border. The user can further adjust them if needed.

- Semi-automatic lesion segmentation. It includes:
    - Highlighting tissues showing significant contrast agent uptake based on an uptake threshold.

    - Semi-automatic segmentation of the suspected lesion identified by the user. The user can further adjust the segmentation if needed or even manually segment the suspected lesion.

    - Automatic computation of the suspected lesion 2D/3D diameter and lesion volume.

- Automatic computation of distances between the suspected lesion and the morphological structures (distances to nipple, chest and skin). The user can further adjust the distances if needed.

- Reporting of user-selected findings and assessment through a dedicated breast report. It includes the option to add annotations based on the Fifth Edition of American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS®) Breast Imaging Atlas. The software automatically reports the localization of the suspected lesion on a dedicated breast sector map. The position can be further adjusted by the user if needed.

- Follow-up for multiple (more than two) studies from same patient. It includes tools to enhance the visualization and analysis of patient follow-up studies through the same layout.

2. BreastLoc

The BreastLoc module is designed to assist users in planning MR-guided breast interventional procedures. Based on user-specified target lesion and fiducial location coordinates, BreastLoc is used to compute and display the following features:

- Needle insertion block position within the grid diagram;
- Needle insertion point activation in the block;
- Depth of introducer, representing the graduation value where to put the depth stop on the introducer sheath;
- Needle insertion path display on native images.

Intended Use / Indications for Use

breastscape V1.0 is an optional image processing software application that is intended for use on Olea Sphere 3.0 software package. It is intended to be used by trained breast imaging physicians and trained MRI technologists.

breastscape V1.0 includes a software module (BreastApp) that supports the visualization, analysis, and reporting of lesions measurements and analysis. breastscape V1.0 supports the evaluation of dynamic MR data acquired during contrast administration and the calculation of parameters related to the uptake characteristics.

breastscape V1.0 performs other user selected processing functions (such as image subtraction, multiplanar and oblique reformats, 3D renderings).

The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image.

breastscape V1.0 can also be used to provide measurements of the segmented tissue volumes (volumes of interest) based on uptake characteristics. These measurements include volume measurement, distances of volumes of interest to anatomical landmarks, 3D longest diameter and 2D long and short axis.

breastscape V1.0 includes the option to add annotations based on the fifth edition of the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS®)

Breast Imaging Atlas.

breastscape V1.0 may be used as an image viewer of multi-modality digital images, including ultrasound and mammography. breastscape V1.0 is not intended for primary interpretation of digital mammography images.

breastscape V1.0 includes a software module (BreastLoc) to assists users in planning MR guided breast interventional procedures. Using information from MR images, regarding user-specified target lesion and fiducial location coordinates, the software gives calculation of the targeted region of interest (such as suspected lesion) depth.

When interpreted by a skilled physician, breastscape V1.0 provides information that may be used for screening, diagnosis, and interventional planning.

Patient management decisions should not be based solely on the results of breastscape V1.0.

Both breastscape V1.0 and MultiView V4.0.3.2 are user-defined software analysis tools used for the visualization, analysis and reporting of MRI studies. Both software tools provide assistance for the users in planning MR guided breast interventional procedures. Furthermore, both software devices support the same limitation of use regarding the display of lossy compressed mammographic images and digitized film screen images that must not be reviewed for primary image interpretations.

Similarly, both devices are for use in hospitals, imaging centers and radiologist reading practices by any trained professional who may require and are granted access to patient image, demographic, and report information. Importantly, neither software product is used for diagnosis. Patient management decisions should not be based solely on the results of either software. Therefore, the intended use of the software is the same.

The only minor difference in the indications for use between the two devices is that breastscape V1.0 is a software application intended to be used on Olea Sphere V3.0 whereas MultiView V4.0.3.2 is a standalone software. breastscape V1.0 is only to be used with the cleared Olea Sphere V3.0 PACS (K152602), which is the reference device. Therefore, this minor difference does not impact the safety or effectiveness of the subject device.

Summary of Technological Characteristics

breastscape V1.0 is an optional PACS software module intended for use with the cleared Olea Sphere V3.0 software package (K152602). breastscape V1.0 accesses MR image series in DICOM format through Olea Sphere V3.0, which is a software package for image viewing, processing and analysis of medical images. The application execution requires Olea Sphere V3.0 with its components (data and license management services) to be started and in operational use.

breastscape V1.0 allows the:

- Visualization (standard image viewing tools, MIPs, and reformats)
- Analysis (registration, subtractions, kinetic curves, parametric image maps, and 3D volume rendering)
- Reporting of user-selected findings and assessment
- Assistance for the users in planning MR guided breast interventional procedures.

- **Breastscape V1.0 versus Multiview V4.0.3.2**

As noted above, both the breastscape V1.0 and MultiView V4.0.3.2 are software analysis tools that are used for the visualization, analysis, and reporting of MRI studies. Both software tools provide assistance for the users in planning MR guided breast interventional procedures. Both software devices are used with combinations of biopsy devices (grids, blocks and MRI-guided vacuum-assisted breast biopsy systems).

Both the breastscape v1.0 and Multivew V4.0.3.2 have similar technological characteristics. The only minor difference is that MultiView V4.0.3.2 is intended to be used with one grid, the Sentinelle grid, and performs automatic detection of the grid and the fiducial. In contrast the breastscape V1.0 is intended to be used with four different grid models: generic, curved lateral access, curved medial access, and Sentinelle grids. Nevertheless, software validation testing demonstrates that the device operates as safely and effectively as its predicate device and does not raise different questions of safety and effectiveness.

As further confirmatory evidence, the company conducted additional validation testing with the subject breastscape V1.0 and predicate MultiView V4.0.3.2 device using anonymized images from a cohort of patients.

- **Breastscape V1.0 versus Olea Sphere V3.0**

As noted previously, the subject breastscape V1.0 will only be used with the company's cleared Olea Sphere V3.0 PACS viewer (K152602).
Additionally, the software architecture of the feature related to kinetics curve computation and parametric image maps of the breastscape V1.0 is identical to the architecture used by the reference device: Olea Sphere V3.0 manufactured by Olea Medical (K152602).

The results of performance evaluation support that the minor difference in the technological characteristics do not raise different questions of safety and effectiveness.

Performance Data

Olea Medical has conducted extensive validation testing of the breastscape V1.0 as a PACS software module intended for use with the Olea Sphere V3.0 system, cleared under K152602. Internal verification and validation testing confirms that the product specifications are met, in support of the substantial equivalence of the intended use and technological characteristic as the reference devices.

breastscape V1.0, as an optional application of the Olea Sphere V3.0 software, has been validated to ensure that the system as a whole provides all the capabilities necessary to operate according to its intended use and in a manner substantially equivalent to the predicate device.

The main groups of tests performed include:

- Product risk assessment;
- Software modules verification tests;
- Software validation test.

Based on the clinical performance as documented in the pivotal clinical study, the breastscape v1.0 has a safety and effectiveness profile that is similar to the predicate device.

In addition to software performance testing, the company conducted additional validation testing to compare the results of breastscape V1.0 with the predicate and reference devices. MultiView™ MR Breast V4.0.3.2 (Hologic®, Bedford, MA, USA) was used as a comparison for BreastLoc™ to evaluate performance of the MR guided breast intervention procedural planning. For BreastApp™, direct manual measurements (ground truth) and Kinetics plugin, viewing tools, follow-up feature, breast dedicated report, mammography loading and visualization, measurements modifications within Olea Sphere V3.0, were used to evaluate the automatically calculated metrics and parametric maps, respectively.

Conclusions

breastscape V1.0 is substantially equivalent to the predicate device: Multiview V4.0.3.2 and similar to the reference device: Olea Sphere V3.0. The breastscape V1.0 has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device.

In addition, the minor technological differences between the breastscape V1.0 and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that the breastscape V1.0 is as safe and effective as the Multiview V4.0.3.2 and Olea Sphere V3.0. Thus, the breastscape V1.0 is substantially equivalent.