MedApp S.A.
% Albert Pacheco
Alliance Network Independent Consultant
PAREXEL International
8 Federal Street
BILLERICA, MASSACHUSETTS 01821

May 1, 2023

Re: K221870
Trade/Device Name: CarnaLife® Holo
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 21, 2023
Received: March 22, 2023

Dear Albert Pacheco:

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,

Jessica Lamb,
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: 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)*
K221870

Device Name
CarnaLife® Holo

Indications for Use *(Describe)*
CarnaLife® Holo is a software device for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements, annotations, and 3D visualization.

Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA-cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency for the country in which it is used.

Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance.

CarnaLife® Holo software is indicated for use by qualified healthcare professionals including, but not restricted to radiologists, non-radiology specialists, physicians, and technicians.

When accessing CarnaLife® Holo software from a wireless stereoscopic head-mounted display (HMD), images viewed are for informational purposes only and not intended for diagnostic use.

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 as Required by 21 CFR 807.92(c)

For CarnaLife® Holo

Date Prepared: April 26, 2023

Submitter: MedApp,S.A.
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30-150 Kraków, Poland

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Proprietary Name: CarnaLife® Holo

Classification: Class II
Medical Image Management and Processing System
21 CFR 892.2050
Product Code: LLZ

Predicate Device: SurgicalAR (K190764)

Reason for Submission: New Device

Device Description

CarnaLife® Holo is a Software as a Medical Device (SaMD) to be used by qualified healthcare professionals including, but not restricted to radiologists, non-radiology specialists, physicians, and technicians for the visualization of medical images in 3D to allow for surgical planning activities. The device makes it possible to visualize 3D Digital Imaging and Communications in Medicine (DICOM) files using volume and surface rendering in 3D to be viewed on a classic display or on a stereoscopic, holographic display. CarnaLife® Holo is intended to be used in operating rooms; office environments within hospitals or at any other location with a computer; and for informational purposes only at any location using the head-mounted display (HMD). The images can be viewed on desktop PCs with a monitor allowing the interaction with CarnaLife® Holo to be performed with a mouse and/or keyboard; and on an HMD, where the interaction with CarnaLife® Holo is performed using hand gestures, voice commands and virtual menus.

CarnaLife® Holo is used to:

- Load patient DICOM data;
- Image review, image manipulation, basic measurements, annotations, and 3D visualization; and
- View DICOM data using a traditional computer monitor, display monitors used for reading medical images for diagnostic purposes, or in mixed reality (MR) using a head-mounted display (HMD).

Indications for Use

CarnaLife® Holo is a software device for display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements, annotations, and 3D visualization.

Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA-cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency for the country in which it is used.

Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance.

CarnaLife® Holo software is indicated for use by qualified healthcare professionals including, but not restricted to radiologists, non-radiology specialists, physicians, and technicians.

When accessing CarnaLife® Holo software from a wireless stereoscopic head-mounted display (HMD), images viewed are for informational purposes only and not intended for diagnostic use.

Substantial Equivalence Discussion

CarnaLife® Holo is substantially equivalent to the predicate device, SurgicalAR (K190764), as both devices have the same intended use and similar technological characteristics. While both devices do not have the same software features, the differences do not raise different questions of safety and effectiveness.

Device Characteristic	**Subject Device: CarnaLife® Holo (K221870)**	**Predicate Device: SurgicalAR (K190764)**	**Comparison**
Classification	Class II	Class II	Same
Product Code	LLZ	LLZ	Same
Indications for Use	CarnaLife® Holo is a software device for display of medical images and other healthcare data. It includes functions for image review image manipulation, basic measurements, and 3D visualization. Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA- cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency	SurgicalAR is a software device for display of medical images and other healthcare data. It includes functions for image review image manipulation, basic measurements, and 3D visualization (MPR reconstructions and 3D volume rendering). Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA-cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency for the country in which it is used.	Same

Device Characteristic	Subject Device: CarnaLife® Holo (K221870)	Predicate Device: SurgicalAR (K190764)	Comparison
	for the country in which it is used. Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance. CarnaLife® Holo software is indicated for use by qualified healthcare professionals including, but not restricted to radiologists, non-radiology specialists, physicians, and technicians. When accessing CarnaLife® Holo software from a wireless stereoscopic head-mounted display (HMD), images viewed are for informational purposes only and not intended for diagnostic use.	Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance. SurgicalAR software is indicated for use by qualified healthcare professionals including, but not restricted to radiologists, non-radiology specialists, physicians, and technologists. When accessing SurgicalAR software from a wireless stereoscopic head-mounted display (HMD) or mobile device, images viewed are for informational purposes only and not intended for diagnostic use.	
Prescription Use or OTC Use	Prescription use	Prescription use	Same
Annotation and Measurement Tools	• Line • Angle • Ruler • Arrow	• Line • Angle • Ruler • Arrow	Same
Data Type Supported	• DICOM • Non-DICOM	• DICOM • Non-DICOM	Same
Image Input Types Supported	• CT/angio CT • MR/4D MR • 3DRA • ECHO • PET • USG	• CT • MR	Different: The difference does not alter intended use and is supported by software verification and validation.
Image View/ Manipulation	• Image Zoom/Zoom • Pan • Window Level • AutoWindow/Presets	• Image Zoom • Pan • Window Level • AutoWindow	Different: The predicate device does

Device Characteristic	Subject Device: CarnaLife® Holo (K221870)	Predicate Device: SurgicalAR (K190764)	Comparison
	• Level • Reset • Scout Lines/Intersection Lines • Image Rotate • Image Flipor Intersection • Image Invert • Magnify	• Level • Reset • Scout Lines • Image Rotate • Image Flip • Magnify	not have the "Image Invert" functionality.
Data Encryption	• HTTPS • SSL	• HTTPS • SSL	Same
Patient Demographic Display	Capable of displaying patient demographic information	Capable of displaying patient demographic information	Same
Data Security	Stored locally on the workstation (PC)	Stored on server	Same
Audit Trail	Audit trail logged	Audit trail logged	Same
File Type Used	• JPEG for lossy data • PNG for lossless data	• JPEG for lossy data • PNG for lossless data	Same
MPR Viewing	This viewing feature enables the display of reformatted CT and MR images into axial, coronal, and sagittal orientations.	This viewing feature enables the display of reformatted CT and MR images into axial, coronal, and sagittal orientations.	Same
3D Volume Rendered Viewing	This viewing feature enables the display of 3D perspective views of CT and MR image sets that have been transformed into volumes. It also provides presets to enable users to alter the visualization parameters of the 3D views to highlight features.	This viewing feature enables the display of 3D perspective views of CT and MR image sets that have been transformed into volumes. It also provides presets to enable users to alter the visualization parameters of the 3D views to highlight features.	Same
Crosshair Navigation and Synchronization	This viewing feature provides a facility to synchronize and scroll through multiple views at the same time.	This viewing feature provides a facility to synchronize and scroll through multiple views at the same time.	Same
Ability to close an image by clicking an "X" in the upper-left portion of the view port	Ability to close an image by clicking an "X" in the examination tab.	Ability to close an image by clicking an "X" in the upper-left portion of the viewport.	Same
Support for TIF Files	Yes	Yes	Same
Support for BMP Files	Yes	No	Different: The difference does not alter intended use and is supported by software verification

Device Characteristic	Subject Device: CarnaLife® Holo (K221870)	Predicate Device: SurgicalAR (K190764)	Comparison
			and validation.
Support of Stored ECHO Data	Yes	No	Different: The difference does not alter intended use and is supported by software verification and validation.
HMD support for informational purposes only (not for diagnostic use)	This viewing feature provides access of CarnaLife® Holo software on consumer, off-the-shelf wireless, Wi-Fi enabled, stereoscopic head-mounted display with minimum of 2GB RAM.	This viewing feature provides access of SurgicalAR software on consumer, off-the-shelf wireless, Wi-Fi enabled, stereoscopic head-mounted display with minimum of 2GB RAM.	Same
Diagnostic quality medical image review	Ability to provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices.	Ability to provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices.	Same

Performance Data

Design validation and verification activities were performed for CarnaLife® Holo as a result of the risk analysis assessment and product requirements. The purpose of software design verification activities was to ensure that the design output specifications met the design input requirements. It is concluded that the design verification was successful in that the design output specifications satisfactorily met the design input requirements.

Design validation was successfully completed, and testing met all predetermined acceptance criteria based on user needs and intended use. Human factors activities were completed per ANSI/AAMI/IEC 62366.

Performance testing included:

- Accuracy of the Measuring function: This testing was conducted using two data sets characterized by different voxel sizes (isotropic and anisotropic data). For each set, points P1, P2, P3 and P4 were defined for both Axial and Coronal projections. Measurement accuracy met specified requirements for the below measurements of distance:
    - X – distance of P1-P2 and P3-P4
    - Y – distance of P1-P3 and P2-P4
    - Angles – defined by points P1-P2-P3
    - Diagonals defined by P1-P4 and P3-P2.

- Accuracy of Volume Rendering: This testing was conducted by performing Volume Rendering on CT scans of two different geometric objects of known size and dimensions. The accuracy of Volume Rendering meeting specified requirements was demonstrated by comparing the size and dimensions of resulting displayed holograms to the known size and dimensions of the two geometric objects.

Conclusion

The performance data demonstrate the CarnaLife® Holo is as safe, as effective, and performs as well as or better than the predicate device, SurgicalAR (K190764). In conclusion, the subject device, CarnaLife® Holo, is substantially equivalent to the predicate device, SurgicalAR (K190764).