CARPL.AI Inc.
% Josh Baker
Consultant
OT Consulting Inc.
33781 Bayside Lane
Dana Point, CA 92629

March 27, 2024

Re: K232891
Trade/Device Name: Carpl (carpl)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 20, 2024
Received: February 20, 2024

Dear Josh Baker:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Jessica Lamb, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232891

Device Name
Carpl (carpl)

Indications for Use *(Describe)*
CARPL, a web-based PACS and radiology workflow management device, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D/3D mammography. It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, PET units, secondary capture tools, imaging gateways. CARPL enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations.

Only pre-processed DICOM images specifically intended for presentation are suitable for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretation on the CARPL. To ensure accurate interpretation, mammographic images should only be evaluated on a monitor that adheres to the technical specifications outlined by the FDA.

This system is designed exclusively for use by proficient and certified medical experts, including physicians, radiologists, and medical technicians.

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.

510(k) Summary

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

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Date Prepared: March 25, 2024

II. DEVICE

Name of Device: Carpl (carpl)
Submission number: K232891
Common or Usual Name: Medical Image Management and Processing System
Classification Name: system, image processing, radiological (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

III. PREDICATE DEVICE

Predicate Device: Augmento (K222781) by DeepTek Medical Imaging Private Limited, Class II, CFR 892.2050, classification with product code LLZ.

IV. DEVICE DESCRIPTION

CARPL, a web-based PACS and radiology workflow management device, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D/3D mammography. It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, PET units, secondary capture tools, imaging gateways. CARPL enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations.

Only preprocessed DICOM "for presentation" images can be interpreted for primary image diagnosis in mammography. Mammographic images with lossy compression and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a display that is cleared, and that meets technical specifications reviewed and accepted by your regulatory authorities. Pre-processing occurs during the transfer of DICOM images from PACS to CARPL Platform involving the filtering of data based on the DICOM tags like “Modality”, “Study Description”, “Accession Number”, etc. This process is aimed at extracting DICOM images that align with the requirements of the deployment workflow. Images that have not undergone this preprocessing are not included in the deployment workflow.
CARPL accepts digital images and information from various sources that adhere to the DICOM

standard. These sources include CT scanners, MR scanners, ultrasound systems, RF Units, PET Units, computed and digital radiographic devices, secondary capture devices, imaging gateways, and other imaging equipment. The system features post-processing elements like MPR/MIP that improve visualization for radiologists, aiding them in the diagnostic assessment and measurement of Computed Tomography (CT) and Magnetic Resonance (MR) images.

When assessing images for diagnostic purposes, it becomes the duty of the healthcare expert to ascertain whether the image quality is appropriate for clinical use. The system offers the choice to incorporate third-party AI models that have been cleared by the FDA. A regulatory compliance team continually oversees and verifies the clearance status of each algorithm. Each algorithm developer must prove regulatory clearances before their products can be incorporated with CARPL. FDA-cleared 3rd party algorithms listed in CARPL display the FDA clearance "K" number along with a hyperlink to the algorithm's FDA clearance URL. The solution solely aids in visualizing the outcomes of these third-party AI models without modifications. The safety and efficacy of the third-party model are governed by the regulatory approval granted to the original manufacturer of the said model.

CARPL's integrated FDA-cleared algorithm list is exclusively managed by CARPL.AI Customers do not have the ability technically or administratively to add or modify which FDA-cleared AI algorithms are integrated with CARPL. Only FDA-cleared algorithms which have passed rigorous regulatory and quality standards review by CARPL.AI Inc. to guarantee functionality, safety and security are made available in CARPL.

CARPL simply presents the simple AI response output, and the initial anonymized image remains consistently available. The duty of evaluating the AI output, validating the results, and conducting the diagnosis lies with competent medical professionals.

CARPL current list of integrated FDA cleared AI Models:

Device Name	**FDA K-Number**	**Company Name**
Lunit INSIGHT CXR Triage	K211733	Lunit Inc
Lunit INSIGHT MMG	K211678	Lunit Inc
Lunit INSIGHT DBT	K231470	Lunit Inc
cmTriage	K183285	CureMetrix, Inc
cmAngio	K232367	CureMetrix, Inc
CINA	K200855, K210237, K22	AVICENNA.AI
qXR-BT	K212690	Qure.ai Technologies
qER-Quant	K211222	Qure.ai Technologies
Qxr-Ptx-Pe	K230899	Qure.ai Technologies
Qxr-Ctr	K231149	Qure.ai Technologies
Qxr-Ln	K231805	Qure.ai Technologies
BoneView	K212365	Gleamer
Rayvolve	K220164	AZmed SAS
CogNet QmTRIAGE	K220080	MedCognetics, Inc.

CoLumbo	K220497	Smart Soft Healthcare AD
KOALA	K192109	IB Lab GmbH
Rbknee	K203696	Radiobotics ApS
Aview Lung Nodule Cad	K221592	Coreline Soft Co.,Ltd.
A View Lcs	K201710	Coreline Soft Co.,Ltd.
Aview	K214036	Coreline Soft Co.,Ltd.
Koios DS	K212616	Koios Medical, Inc.
DrAid for Radiology v1	K221241	VinBrain Joint Stock Company
InferRead CT Stroke.AI	K211179	Infervision Medical Technology Co., Ltd
InferRead Lung Ct.Ai	K192880	Infervision Medical Technology Co., Ltd
Icobrain	K192130, K161148, K180326, K181939, K192962	Icometrix NV
HALO (LVO Triaging detection)	K200873	NiCo-Lab B.V.
MammoScreen® 2.0	K211541	Therapixel
LiverSmart	K213776	Resonance Health Analysis Servi
Cercare Medical Neurosuite	K202793	Cercare Medical ApS
Us2.v1	K210791	Us2.Ai
Annalise Enterprise Cxr Triage Trauma	K222268, K222179	Annalise-AI Pty Ltd
Annalise Enterprise Cxr Triage Pneumothorax	K213941	Annalise-AI Pty Ltd
Clearread +Confirm	K123526	RIVERAIN TECHNOLOGIES
Clearread Ct	K221612, K161201	RIVERAIN TECHNOLOGIES
WRDensity	K202013	Whiterabbit.Ai Inc.
Claripulmo	K203783	ClariPi Inc.
Transpara Density 1.0.0	K232096	Screenpoint
Veolity	K201501	MeVis
VUNO Med-DeepBrain	K231398	VUNO Inc.

CARPL incorporates the following:

1. The setup includes a Gateway, situated on the client's end within the modality/PACS network, which can be implemented using the widely available conventional TCP/IP network framework in healthcare institutions. This Gateway is set up on a computer having a reliable internet connection for online transmission, or it can be linked to a Local Area Network (LAN) to transmit images within the network. The Gateway is responsible for collecting DICOM images from different DICOM-compliant sources, forwarding them to the CARPL platform. Additionally, it accepts secondary capture images from CARPL and relays them to the linked hospital PACS.
2. It has a dataset manager i.e., study list, which includes all the studies that are uploaded to the system.
3. It has a radiology workflow management system. Supervisors or project Managers can assign the studies to Radiologists. Radiologists can then view the study images, diagnose them, and share feedback on CARPL Viewer.
4. It is used by radiologists to view the DICOM images for diagnosis and sharing feedback. The viewer supports DICOM images from Digital X-Ray (DX), Computerized Radiography (CR), Ultrasound (US), Computed Tomography (CT), Magnetic Resonance (MR), Nuclear Medicine (NM), Digital Mammography (MG), Positron Emission Tomography (PET), Radiographic imaging (RG), Radio Fluoroscopy (RF) and X-Ray Angiography (XA).
5. It only incorporates algorithms that have received FDA clearance. The inclusion of KNumber is obligatory and serves as an authentication factor during the integration process. CARPL verifies the 510 (k) Number against the 510 (k) Number database before proceeding with integration.
6. The system forwards the input study to the third-party AI model, obtains the AI-generated results, and presents these results directly in the Viewer. This enables Radiologists to visualize and utilize the outputs from the third-party AI model to aid in diagnosing the study. The displayed outcomes adhere to the regulatory clearance specifications of the third-party provider. The original image remains accessible at all times.
7. It can provide status for the studies in the dataset list based on the outputs provided by the 3rd party AI models.
8. It displays the output of the 3rd party AI model in the Viewer for visualization by the Radiologist to assist in diagnosing the study.
9. It provides radiologists MPR/MIP 2D multi-planar reconstruction post-processing elements, enhancing visualization and aiding in diagnostic analysis.
10. CARPL also provides a list of annotation tools that the user can use to annotate a case and carry out measurements. The following tools are provided by CARPL:
    a. Length : The user can use this to measure the distance of the suspected lesion from point ‘A’- ‘B’, which is expressed in cm. The user places the cursor over the starting point on a lesion and drags to draw a segment with visible measurement. To finish the segment, the user releases the cursor. If need be, the user can move the entire segment or the measurement value to a convenient place.
    b. Annotate : Users can mark a suspected lesion on the image. After the user finishes the marking, a pop-up appears on the image from which the user can select a label or write a label on the annotated area.

c. Angle : Angle tool can be used when a user wants to measure the angle of a ROI. The user, from a left button on the mouse, draws the first arm of the angle and releases it, and similarly draws the second arm, after which the value is displayed in degrees.
d. Bidirectional : It is a tool to measure ROI's length and width. The user annotates a suspected lesion, e.g., Nodule; using this tool the user can have the length and width of the marked ROI. The user drags the cursor to a position where they think ROI is present. The values are displayed in mm.
e. Ellipse : This tool helps users mark an ROI on an image in a defined elliptical border. The user draws an ellipse by dragging the mouse cursor on the ROI and releasing it to finish the Ellipse. Once an ellipse is completed, a pop-up appears to label the ROI. Users can also move the Ellipse to a different position by dragging it.
f. Rectangle : Similar functions to Ellipse. The only difference is the shape of the ROI- which appears as a rectangle.
g. Freehand/Close polygon : This is used for giving a freehand shape to an ROI. The user clicks on the left button on the mouse to create a starting node on the ROI; the user then drags the node and finishes it where they want to end the node around the ROI. A pop-up then appears to label the ROI. Users can edit the final shape by clicking on the drawing and dragging it to the desired position.
h. Eraser: The user can click on the marked ROI and erase it.
i. Reset: This button restores the study image to its original state.

11. All significant events within the application trigger Smart Notifications to be distributed to every registered or non-registered user. These notifications do not pertain to any potentially suspected findings that might be recognized by the FDA-cleared third-party AI models, which can be optionally integrated with CARPL.
12. It provides a communication feature to all the users associated with a given study.
13. An RDBMS is employed for data storage, while an object storage server is utilized for the purpose of storing and retrieving DICOM images and thumbnails.

The utilized network protocol involves TLS-based communication with HTTPS and AES encryption.

V. INDICATIONS FOR USE

CARPL, a web-based PACS and radiology workflow management device, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D/3D mammography. It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, PET units, secondary capture tools, imaging gateways. CARPL enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations.

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This system is designed exclusively for use by proficient and certified medical experts, including physicians, radiologists, and medical technicians.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject and predicate devices are both medical image management and processing systems, which are indicated for medical image management, review, and data distribution. The subject device and the predicate device are substantially equivalent in the areas of general function, application, and intended use. Any differences between the subject and predicate devices have no negative impact on the device safety or efficacy and does not raise any new potential or increased safety risks and is equivalent in performance to existing legally marketed devices.

	Features compared	Subject Device (CARPL) K232891	Predicate Device (Augmento) K222781	Significant Differences?
		General Information		
1.	Manufacturer	CARPL.AI Inc	DEEPTEK MEDICAL IMAGING PRIVATE LIMITED	-
2.	Common Name	Medical image management and processing system	Medical image management and processing system	NO
3.	Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	NO
4.	Classification	Class II	Class II	NO
5.	Regulation number	21 CFR 892.2050	21 CFR 892.2050	NO
6.	Product Code	LLZ	LLZ	NO
7.	Indications For Use	CARPL, a web-based PACS and radiology workflow management device, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D/3D mammography. It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass	Augmento is a web-based PACS and radiology workflow management solution. It receives digital images and data from various DICOM compliant sources (i.e. CT scanners, MR scanners, ultrasound systems, RF Units, PET Units, computed & digital radiographic	NO

		a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, PET units, secondary capture tools, imaging gateways. CARPL enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations. Only pre-processed diagnostic DICOM “for presentation” images can be interpreted for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretation on the CARPL. To ensure accurate interpretation, mammographic images should only be evaluated on a monitor that adheres to the technical specifications outlined by the FDA. This system is designed exclusively for use by proficient and certified medical experts, including physicians, radiologists, and medical technicians.	devices, secondary capture devices, imaging gateways and other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and/or across computer networks at distributed locations. Only preprocessed DICOM "for presentation" images can be interpreted for primary image diagnosis in mammography. Lossy compressed images and digitized film screens of mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by the FDA. This system is meant to be used by trained and qualified medical professionals, e.g physicians, radiologists, nurses, and medical technicians.	

	Features compared	Subject Device (CARPL) K232891	Predicate Device (Augmento) K222781	Significant Differences?
Specifications				
8.	Modalities	Various Image sources	Various image sources	NO
9.	Web browser software	Google Chrome, Mozilla, and Edge	Google Chrome, Mozilla, and Edge	NO
10.	Resolution	32 bit Color Display & 1920x1080	32 bit Color Display & 1920x1080	NO
11.	Image Storage	YES	YES	NO
12.	Software environment	OS: Windows 10 or higher	OS: Windows 10	NO - No significant difference in the operating environment used. The subject device and the predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. Therefore, it is our determination that there is “No impact on safety or efficacy” and there are no new potential safety risks.

	Features compared	Subject Device (CARPL) K232891	Predicate Device (Augmento) K222781	Significant Differences?
		Functions		
13.	Main Functions	• Log In • Worklist – Search Filter • Worklist – Open image • Work list – study List • Worklist – Report • Worklist – Series • Viewer – View exam • Viewer – Control View window • Viewer – view mode (real resolution) • Viewer – View mode (Highlight) • Viewer – Stacking • Viewer – Changing the layout • Viewer – Comparative study • Viewer – Preset filter • Viewer - Zoom • Viewer – Panning • Viewer - Invert Image • Viewer – Viewing mode (Normal/ Image/ Stack/ Custom/ Annotation) • Viewer – Comparative study • Viewer – Rotation • MIP/MPR	• Log In • Worklist – Search Filter • Worklist – Open image • Work list – study List • Worklist – Report • Worklist – Series • Viewer – View exam • Viewer – Control View window • Viewer – view mode (real resolution) • Viewer – View mode (Highlight) • Viewer – Stacking • Viewer – Changing the layout • Viewer – Comparative study • Viewer – Preset filter • Viewer - Zoom • Viewer – Panning • Viewer - Invert Image • Viewer – Viewing mode (Normal/ Image/ Stack/ Custom/ Annotation) • Viewer – Comparative study	NO

		Reconstruction ● Viewer – Reference line ● Viewer – Sharpening ● Viewer – Measure ● Viewer – Inverting image color ● Viewer – Cine ● Viewer- Overlaying.	● Viewer – Rotation ● MIP/MPR Reconstruction ● Viewer – Reference line ● Viewer – Sharpening ● Viewer – Measure ● Viewer – Inverting image color ● Viewer – Cine ● Viewer- Overlaying.	
14.	3D Cursor	YES	YES	NO
15.	Optional Integration of FDA - cleared 3rd party AI models	YES	YES	NO
16.	Operation feature	● Web environment-based PACS. ● Viewing and handling DICOM medical images. ● Review and report study located on a server ● View multiple AI model output	● Web environment based PACS ● Viewing and handling DICOM medical images. ● Review and report study located on a server	NO - There are no significant differences in the operation features. The subject device and the predicate device are substantially equivalent in the areas of general function, application, and intended use and the ability to view multiple AI model output does not raise any new potential safety risks.

The technological principle for both the subject and predicate devices is the same in terms of prescription use, support of various modalities, resolution, image storage, use of the DICOM Standard, 3D Cursor, and Operation features. Most of the features, specifications, and functions of both the subject and predicate devices, like indications for use, software web browser, software intended environment, study viewer, and study worklist are similar.

CARPL provides the feature of optional integration with external FDA-cleared 3rd party AI models like the predicate device Augmento does. The integration with the FDA-cleared 3rd party AI models is optional based on the user's discretion, and always in accordance with the 3rd party manufacturer's regulatory clearance. The regulatory status of integrated FDA approved algorithms is clear in the CARPL user interface as it displays the approved algorithm's 510(k) number along with a link to the FDA website page containing the algorithm's substantial equivalence ruling. Technological safeguards prevent algorithms without FDA clearance from being employed. Hence, the difference does not affect the product effectiveness and safety.

VII. PERFORMANCE DATA

Non-clinical testing:

CARPL has been assessed and tested at the factory and has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate output functions and actions performed by CARPL.AI Inc. and followed the process documented in the Validation Test Plan. Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Summary:

Based on the performance as documented in the Validation Testing, CARPL, was found to have a safe and effectiveness profile that is substantially equivalent to the predicate device.

The following Standards were used to develop CARPL, and the device has met all the requirements listed in the Standards except for inapplicable requirements:

Standard Developing Organization	Standard Designation Number and Date	FDA Recognition Number	Title of Standard
NEMA	PS 3.1 - 3.20 2022d	12-349	Digital Imaging and Communications in Medicine (DICOM) Set
IEC	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	13-79	Medical device software - Software life cycle process
IEC	60812 Edition 3.0 2018-08	5-120	Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)

VIII. CONCLUSION

The information presented in the 510(k) for CARPL contains adequate information, data, and nonclinical test results to demonstrate substantial equivalence to the predicate device. CARPL was shown to be substantially equivalent to the predicate device in the areas of technical characteristics, general function, application, and intended use and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.