



February 6, 2026

Live Medica LLC
% Danielle Short
Regulatory Consultant
MEDicept, Inc.
200 Homer Ave.
Ashland, Massachusetts 01721

Re: K253927

Trade/Device Name: LiveMedica Enterprise PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 8, 2025
Received: December 8, 2025

Dear Danielle Short:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253927

?

Please provide the device trade name(s).

?

LiveMedica Enterprise PACS

Please provide your Indications for Use below.

?

LiveMedica Enterprise PACS is a system for distributing, viewing, processing and archiving medical images within and outside healthcare environments. The LiveMedica Enterprise PACS server receives image data in DICOM format via the hospital network. This provides universal connections to archives, modalities, and workstations. The supported modalities are listed in the DICOM Conformance Statement.

LiveMedica Enterprise PACS is to be used only by trained and instructed health care professionals. It can support physicians and/or their medical staff in providing their own diagnosis for medical cases. The final decision regarding diagnosis, however, resides with the doctor and/or their medical staff in their own area of responsibility.

Although the web and technologies allow the software to run on a variety of hardware platforms, for diagnostic purposes the user must make sure that the display hardware used for reading the images complies with state-of-the-art diagnostic requirements and currently valid laws.

Only DICOM for presentation images can be used on an FDA approved monitor for mammography for primary image diagnosis.

Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

K253927
510(k) Summary

DATE PREPARED

February 3, 2026

MANUFACTURER AND 510(k) OWNER

Live Medica LLC
 2301 Sunnystone Way
 Raleigh, NC 27613
 Official Contact: Nick Ponder, COO

REPRESENTATIVE/CONSULTANT

Danielle Short
 MEDIcept
 Telephone: (610)-304-4614
 Email: dshort@medicept.com

DEVICE INFORMATION

Proprietary Name/Trade Name: LiveMedica Enterprise PACS
 Common Name: Medical Image Management and Processing System
 Regulation Number: 21 CFR 892.2050
 Class: II
 Product Code: LLZ
 Review Panel: Radiology

PREDICATE DEVICE IDENTIFICATION

510(k) Number	Predicate Device Name / Manufacturer	Predicate/Reference
K082269	VISAGE PACS6.0/CS 3.1	Predicate

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

LiveMedica Enterprise PACS is a Picture Archiving and Communication System designed to store, retrieve, manage and display DICOM-compliant medical images for diagnostic imaging workflows across hospitals, imaging centers and multi-site healthcare networks. It includes functionality for server-side image rendering, centralized and edge-based study management and routing. The system is to be used by trained healthcare professionals to perform advanced image manipulations, including zoom, pan, window/level adjustments, annotations, measurements and more. LiveMedica Enterprise PACS supports DICOM conformance, HL7/FHIR-based interoperability and integrates with HIS/RIS/EMR systems.

INTENDED USE

LiveMedica Enterprise PACS is a system for distributing, viewing, processing and archiving medical images within and outside healthcare environments. The LiveMedica Enterprise PACS server receives image data in DICOM format via the hospital network. This provides universal connections to archives, modalities, and workstations. The supported modalities are listed in the DICOM Conformance Statement.

LiveMedica Enterprise PACS is to be used only by trained and instructed health care professionals. It can support physicians and/or their medical staff in providing their own diagnosis for medical cases. The final decision regarding diagnosis, however, resides with the doctor and/or their medical staff in their own area of responsibility.

Although the web and technologies allow the software to run on a variety of hardware platforms, for diagnostic purposes the user must make sure that the display hardware used for reading the images complies with state-of-the-art diagnostic requirements and currently valid laws.

Only DICOM for presentation images can be used on an FDA approved monitor for mammography for primary image diagnosis.

Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

LiveMedica believes that the LiveMedica Enterprise PACS is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use and similar indications for use. The subject device has the same and/or similar technological characteristics as the device cleared in K082269. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

<i>Characteristic</i>	<i>Subject Device LiveMedica Enterprise PACS</i>	<i>Predicate Device VISAGE PACS 6.0/CS 3.1 K082269</i>	<i>Equivalence</i>
Intended Use and Indications for Use	LiveMedica Enterprise PACS is a system- for distributing, viewing, processing, and archiving medical images within and outside health care environments. The LiveMedica PACS server receives image data in	Visage PACS/CS is a system- for distributing, viewing, processing, and archiving medical images within and outside health care environments. The Visage PACS/CS server receives image data in DICOM format via the hospital network. This provides universal connections to	Same intended use and similar indications for use.

<i>Characteristic</i>	<i>Subject Device</i> LiveMedica Enterprise PACS	<i>Predicate Device</i> VISAGE PACS 6.0/CS 3.1 K082269	<i>Equivalence</i>
	<p>DICOM format via the hospital network. This provides universal connections to archives, modalities, and workstations. The supported modalities are listed in the DICOM Conformance Statement.</p> <p>LiveMedica Enterprise PACS is to be used only by trained and instructed health care professionals. It can support physicians and/or their medical staff in providing their own diagnosis for medical cases. The final decision regarding diagnoses, however, resides with the doctors and/or their medical staff in their own area of responsibility.</p> <p>Although the web and thin client technologies allow the software to be run on a variety of hardware platforms, for diagnostic purposes the user must make sure that the display hardware used for reading the images complies with state-of-the-art diagnostic requirements and currently valid laws.</p> <p>Only DICOM for presentation images can be used on an FDA approved monitor for mammography</p>	<p>archives, modalities, and workstations. The supported modalities are listed in the DICOM Conformance Statement.</p> <p>Besides general image interpretation and processing tools, Visage PACS/CS provides specific tool sets for several clinical applications, including:</p> <ul style="list-style-type: none"> - CT/MR angiography, e.g. for vascular analysis and stent planning - Cardiac analysis, including calcium scoring and functional assessment of cardiac CT data -Neuroradiology, including CT and MR brain perfusion analysis -Oncology, including SUV analysis and lesion marking and analysis <p>Visage PACS/CS is to be used only by trained and instructed health care professionals. It can support physicians and/or their medical staff in providing their own diagnosis for medical cases. The final decision regarding diagnoses, however, resides with the doctors and/or their medical staff in their own area of responsibility.</p> <p>Although the web and thin client technologies allow the software to be run on a variety of hardware platforms, for diagnostic purposes the user must make sure that the display</p>	

<i>Characteristic</i>	<i>Subject Device LiveMedica Enterprise PACS</i>	<i>Predicate Device VISAGE PACS 6.0/CS 3.1 K082269</i>	<i>Equivalence</i>
	for primary image diagnosis. Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.	hardware used for reading the images complies with state-of-the-art diagnostic requirements and currently valid laws. Only DICOM for presentation images can be used on an FDA approved monitor for mammography for primary image diagnosis. Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.	
Product Codes and Regulation Number	LLZ 21 CFR 892.2050	LLZ 21 CFR 892.2050	Same
Image file formats	DICOM 3.0	DICOM 3.0	Same
Image Acquisition and Communication	DICOM Compliant	DICOM Compliant	Same
Supported Modalities	CR, CT, DR, DX, ES, ECG, GM, IO, MG, MR, NM, PT, OT, RF, RT, US, XA, XC	CR, CT, DR, DS, DX, ES, GM, IO, MG, MR, NM, PT, OT, RF, RT, US, XA, XC	Similar
Image Processing	Server-Side Rendering	Server-Side Rendering	Same
Operating System	Windows	Windows	Same
Intended Users	Trainer Healthcare Professionals	Trained Healthcare Professionals	Same

<i>Characteristic</i>	<i>Subject Device LiveMedica Enterprise PACS</i>	<i>Predicate Device VISAGE PACS 6.0/CS 3.1 K082269</i>	<i>Equivalence</i>
Image Manipulation Functions	<ul style="list-style-type: none"> • Zoom • Quad Zoom • Magnify • Pan • Window Level • Contrast Enhance • Invert Color • Palette • Context Tool • Flip Horizontal • Flip Vertical • Rotate Right • Rotate Left • Bone Enhancement • Simple MPR • MPR • MIP • MinIP • AVG • Fusion • Reset Frame 	<ul style="list-style-type: none"> • Zoom • Quick Zoom • Magnifying glass • Pan • Window Leveling • Edge enhancement • Grayscale Inversion • Rotating, flipping • MPR,MIP • Bone removal • Fusion • Side-by-side Registration • Volume Measurement 	Similar
Measurement	<ul style="list-style-type: none"> • Line • Ratio of length • Measure Compare • Center Point • Radial Length • Ellipse Area • Rectangle Area • Cardiothoracic Ratio • Cobb Angle • HO Angle • Freehand ROI • Perfect Circle • Three Point Angle • Point Pixel • Spine label • 3D Point • 3D Measure • 3D Angle • 3D Cursor • 3D Spine Label • Cineplay • Calibration 	<ul style="list-style-type: none"> • Distance • Angulation • Area • Greyscale density • Manual distance calibration • Cine Mode • 3D visualization of 3D image series with gantry tilt • Automatic generation of thick slices 	Similar

<i>Characteristic</i>	<i>Subject Device LiveMedica Enterprise PACS</i>	<i>Predicate Device VISAGE PACS 6.0/CS 3.1 K082269</i>	<i>Equivalence</i>
Hardware Requirements for Server	<p>Minimum Spec for Application server (<100k studies/year)</p> <p>CPU: 16 vCPU RAM: 32 GB Disk: 500 GB SSD (RAID-10) Storage: 10 TB SAN/NAS RAID-6 IOPS ≥ 10K+ scalable SAN/NAS</p> <p>Database server</p> <p>CPU: 16 vCPU RAM: 32 GB</p>	<p>PC 2X Pentium III 1,4 Ghz or PC 1x Pentium IV 3GHz (Hyperthreading),</p> <p>≥ 1GB RAM 2x 60 GB Harddisk SCSI or SATA</p>	Similar
Software Requirements for Server	<p>Window Server 2022/Ubuntu 24.04</p> <p>PostgreSQL RabbitMQ Redis Erlang Apache Kafka Nginx Openrestry</p>	<p>Windows 2003 Server Internet Explorer 6</p>	Similar
Workflow Features – Database Filter, DICOM query/retrace from archives and workstations, change assignment of patients	Yes	Yes	Same

Based on the technological characteristics, it can be concluded that the subject device is substantially equivalent to the predicate device.

SUMMARY OF NON-CLINICAL TESTING

The software was developed per the following standards:

- IEC 62304:2015 Medical Device software – software life cycle process
- ISO 14971:2019 Medical Devices – Application of risk management to medical devices

The device meets the following voluntary standards:

- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in medicine (DICOM) Set. (Radiology), 2024e
- ISO IEC 10918-1, Information technology – Digital compression and coding of continuous-tone still images: Requirements and guidelines

The device underwent verification and validation testing according to the following guidance documents:

- Content of Premarket Submissions for Device Software Functions, Issued June 2023
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Issued June 2025

The results of these tests indicate that the subject device is safe, effective, and substantially equivalent to the predicate device.

CONCLUSION

The LiveMedica Enterprise PACS is concluded to be substantially equivalent to the predicate device based on the testing performed, similar indications for use with the same intended use, and similar technological characteristics. It can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate device.