



Syneris
Lily Timonina
Regulatory Affairs Manager
1600 Steeles Ave. W., Suite 214
Concord, ON L4K 4M2
Canada

September 23, 2026

Re: K261874
Trade/Device Name: Syneris PACS v.1.0.1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 2, 2026
Received: September 3, 2026

Dear Lily Timonina:

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.

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. In the background, there is a large, light blue, semi-transparent watermark of the letters "FDA".

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.

K261874

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Please provide the device trade name(s).

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Syneris PACS v.1.0.1.0

Please provide your Indications for Use below.

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Syneris PACS is a software device intended to be used by healthcare personnel and intended for viewing, reviewing, performing measurements/quantifications and reporting of medical images and data acquired from DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy images and digitized film images must not be used for primary diagnosis or interpretation.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

☒ Neonates/Newborns (Birth to < 29 days old)

☒ Infants (29 days old to < 2 years old)

☒ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) summary

K261874

1. Submitter

Name	Syneris
Address	1600 Steeles Avenue West, Suite 214, Concord, Ontario, L4K 4M2, Canada
Phone	(416) 699 4125
Email	lily.timonina@synerishealth.com
Contacts	Lily Timonina, Regulatory Affairs
Date Prepared	2026-08-20

2. Subject Device

Trade Name	Syneris PACS v.1.0.1.0
K Number	K261874
Common Name	Picture Archiving Communications System
Regulation Number	21 CFR 892.2050
Regulatory Class	II
Product Code	LLZ
Review Panel	Radiology

3. Predicate Device

Trade Name	ONIS-PACS System
K Number	K181318
Common Name	Picture Archiving Communications System
Regulation Number	21 CFR 892.2050
Regulatory Class	II

Product Code	LLZ
Review Panel	Radiology

4. **Device Description**

Syneris is a software-as-medical-device Picture Archiving and Communication System (PACS) designed for radiologists to view, interpret, and manage medical imaging studies. The system operates in compliance with DICOM standards for medical imaging and uses HTTPS for secure communication between its components.

The Syneris PACS receives, organizes, and displays patient images for diagnostic review. It includes structured viewing, measurement, annotation, and reporting features tailored to different specialties, such as orthopedics, cardiology, and nuclear medicine. It supports a wide range of DICOM modalities and enables work across multiple monitors using a workspace organized via Hanging Protocols.

The system includes logging and encryption modules and interacts with external systems such as RIS and imaging modalities.

5. **Indications For Use**

Syneris PACS is a software device intended to be used by healthcare personnel and intended for viewing, reviewing, performing measurements/quantifications and reporting of medical images and data acquired from DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy images and digitized film images must not be used for primary diagnosis or interpretation.

6. **Comparison Of Technological Characteristics With The Predicate Device**

Both the subject (Syneris PACS) and predicate (ONIS-PACS) devices are Picture Archiving Communications Systems, which are indicated for medical image management, review, and data distribution. Both systems have been developed to replace traditional film handling in radiology.

Syneris PACS is substantially equivalent to the identified predicate device ONIS-PACS (K181318) in the following areas:

- Both devices fall under the 892.2050 regulation classification.
- Both devices fall under the LLZ product code for Automated Radiological Image Processing Software.
- Both devices have similar indications for use, as described in the Substantial Equivalence Comparison Table below.

- Both devices have similar technological characteristics, as described in the Substantial Equivalence Comparison Table below.

Functionality	Subject Device	Predicate Device	Justification for Differences
Trade Name	Syneris PACS	ONIS-PACS	N/A
Manufacturer	1000935486 ONTARIO INC.	DigitalCore Co., Ltd	N/A
510(k) Number	K261874	K181318	N/A
Classification	Device Class:II Product Code: LLZ 21 CFR 892.2050	Device Class:II Product Code: LLZ 21 CFR 892.2050	Equivalent
Indications for Use	Syneris PACS is a software device intended to be used by healthcare personnel and intended for viewing, reviewing, performing measurements/quantifications and reporting of medical images and data acquired from DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy images and digitized film images must not be used for primary diagnosis or interpretation.	ONIS-PACS is a software device intended to be used by healthcare personnel and intended for viewing, reviewing, performing measurements/quantifications and reporting of medical images and data acquired from DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy images and digitized film images must not be used for primary diagnosis or interpretation.	Equivalent, both devices are software only devices intended to allow clinicians to view and process DICOM images, and communicate results over a network. Both devices provide support for mammographic images, and both devices contraindicate that lossy images should not be used for primary diagnosis nor interpretation.
Device Description and Key Components	Syneris PACS software is a Picture Archiving Communication System suitable for storing, distributing, visualizing, and manipulating DICOM images.	ONIS-PACS is a Picture Archiving Communication System (PACS) fully compliant with the DICOM version 3.0 Standard. It is suitable for storing, distributing, retrieving,	Comparable components: - desktop viewer application (Viewer and ONIS Viewer) - DICOM retrieval application

	Syneris System is comprised of the following interrelated software components: Viewer is a desktop application that provides navigation and visualization of multimodality and multidimensional images and acts as a DICOM viewer capable of connecting to a DICOM network. Viewer Provider component is responsible for fetching medical images from the storage system or DICOM server and delivering them to the Viewer. DICOM Server manages the storage and exchange of medical images and related information using the DICOM standard. Worklist Assistant provides multi-clinic worklist navigation and credential management, launching selected studies into the Viewer. Cloud Infrastructure provides scalable, off-site storage and management of medical images and data, accessible via the internet.	visualizing, manipulating, performing measurements/quantifications and reporting various DICOM objects. ONIS Viewer is a desktop application that makes it possible to visualize, manipulate and process medical images of many different modalities. ONIS Remote is a desktop application identical to the ONIS Viewer, except that it runs without the Local Server. WebONIS is an ActiveX component loaded into an HTML page that provides the same functionality as the ONIS Remote application. ONIS Site Server is a server application that supports the storage and retrieval of a wide range of DICOM Storage objects. ONIS Organization Server is a server that provides a single access point to multiple Site Servers.	(Provider and Local Server) - local DICOM server (DICOM Server and ONIS Site Server) Both devices include server-side distributed-access components. The specific implementation differs: ONIS-PACS uses Site Server and Organization Server components, while Syneris PACS uses cloud/server-hosted infrastructure, Viewer Provider, DICOM Server, databases, and storage components. While there is no direct equivalent of the ONIS Remote application, the Syneris Viewer provides comparable remote/distributed viewing functionality through connection to the Syneris backend/cloud infrastructure. There is no direct equivalent of a browser-based WebONIS component. This represents a difference in access method and a subset of the predicate's access modes. The absence of a browser-based viewer
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			does not raise different questions of safety or effectiveness because diagnostic image review is performed through the validated Syneris desktop Viewer.
Device Property	SaMD	SaMD	Equivalent
Intended User	Physicians or other licensed practitioners in healthcare institutions	Physicians or other licensed practitioners in healthcare institutions	Equivalent
Prescription / OTC Use	Prescription Use	Prescription Use	Equivalent
Technological Characteristics			
System Architecture	Software-only device comprising workstation software and server-side software	Software-only device comprising workstation, web, and server software	Comparable. Both devices are software-only PACS systems with viewer/workstation and server-side components for DICOM image storage, retrieval, communication, display, manipulation, measurement/annotation, and reporting. Syneris uses a cloud/server-hosted architecture and does not include a browser-based ActiveX WebONIS component. This is an implementation difference and does not introduce a new clinical function or different question of safety or effectiveness.
Operating System	Windows 10, 11	Windows 7, 8, 10 Microsoft Windows 2008 Server Standard Microsoft Windows	Equivalent

		2012 Server Standard	
Functions and Capabilities			
Data Access and Communication with Connected Systems	Yes. Syneris PACS supports system-managed exchange of images, reports, patient/encounter data, and related clinical information with configured connected systems, including DICOM-compliant imaging devices and site-configured RIS/CIS/EMR systems, as applicable. These exchanges are performed through configured Syneris interfaces and workflow, not through direct user-controlled local file upload/download from within the Viewer.	Yes. ONIS-PACS supports DICOM-based data access and communication with connected systems, including DICOM servers, PACS workstations, ONIS Site Server, and ONIS Organization Server.	Comparable for networked PACS data communication. Both devices support exchange of medical images and related data across connected clinical/networked systems, although the specific implementation differs. Syneris uses configured server/cloud and clinical-system interfaces, while ONIS includes direct DICOM/server, local media, and direct user-controlled import/export functions. These differences do not raise different questions of safety or effectiveness because both devices support the intended PACS workflow of making medical images and related data available for clinical review, measurement/annotation, and reporting.
Data Output	Syneris PACS supports system-managed output and distribution of images, reports, patient/encounter data, and related clinical information through configured connected-system interfaces. Syneris PACS does not provide direct in-Viewer local	ONIS-PACS supports export of images to various image formats, local filesystem/media export, PACS transfer, and printing functions as described in the predicate documentation.	Comparable for the intended PACS communication workflow, with differences in implementation. Syneris uses configured system interfaces for clinical data output and distribution, while ONIS also provides

	image/report export and does not support DICOM Print Management.		direct user-controlled local/media export and printing functions. The absence of direct in-Viewer local export and DICOM Print Management does not raise different questions of safety or effectiveness because these functions are not required for Syneris PACS's intended use.
DICOM Storage and Modality Worklist Communication	Supports DICOM Storage and Modality Worklist-related communication as described in the DICOM Conformance Statement. Syneris PACS does not support DICOM Query/Retrieve services, including Query/Retrieve C-FIND, C-MOVE, or C-GET, and does not support DICOM Print Management.	Supports DICOM communication functions, including DICOM storage/retrieval functions, as described in the predicate device documentation.	Comparable. Syneris PACS supports the DICOM services required for image receipt, worklist-related communication, storage, display, measurement, annotation, reporting, and distribution through its validated system architecture. The absence of DICOM Query/Retrieve and DICOM Print Management does not raise different questions of safety or effectiveness because those services are not required for the subject device's intended use and workflow.
Hanging Protocols	Yes	Yes	Equivalent
Image Visualization	Supports 2D, Mammography, Multi Planar Reconstruction (Axial, Sagittal, Coronal), Maximum Intensity Projection, and volume rendering through 3D cursor	Supports 2D, Mammography, Multi Planar Reconstruction (Axial, Sagittal, Coronal), Maximum Intensity Projection, and Volume Rendered views	Equivalent, both devices provide standard rendering tools

Image Manipulation Tools	Supports W/L, zoom, pan, stack, 1:1 scale, rotate, flip, invert, brightness/contrast, magnifying glass	Supports W/L, zoom, pan, stack, move, rotate, flip, color LUT, opacity table, image filters	Equivalent, both devices provide standard image manipulation tools
Measurement Tools	Supports distance and angle measurements, path length measurements, and regions of interest measurements	Supports distance and angle measurements, and pixel statistics for user-drawn regions of interest	Equivalent, both devices provide standard measurement tools
Orthopaedic measurement tools	Cobb angle, acetabular index, Sharp angle, centre-edge angle, Reimer index.	Named indices not provided. Provides angle between segments, ratio between segments, parallel and orthogonal segment construction, and segment calibration.	Comparable. The predicate provides every primitive from which these indices are derived — the angle between two user-placed segments, the ratio between two user-placed segments, and orthogonal construction — but not the named indices, which the user would identify and calculate from the same measurements. The subject device applies the published formula to the same user-placed geometry, reducing calculation and transcription error. No automated analysis or interpretation is introduced and the intended use is unchanged.
Cardiac measurement tools	Doppler velocity, Doppler time, Doppler trace, Doppler deceleration, cardiac area and volume	Not provided.	Difference. These measurements are routinely performed on the acquiring ultrasound system at the time of acquisition. The subject device reproduces them from the same image

			data, using calipers or a contour placed by the user and scaled by the DICOM region calibration data supplied by the acquiring system. No automated analysis or interpretation is introduced, and the intended use is unchanged, so this difference does not raise different questions of safety or effectiveness.
PET-CT display	Fusion display with adjustable fusion ratio, colour scheme, gamma and fusion/maximum levels. Does not compute SUV or any quantitative uptake metric.	Displays PET images.	Different. Fusion display is a presentation function: it superimposes two registered series for simultaneous review and does not derive, quantify or interpret radiotracer uptake, nor does it alter the diagnostic information present in either series. The difference does not raise different questions of safety or effectiveness.
Annotation Tools	Supports text, arrow, angle, line, ellipse	Supports text, arrow, angle, line and other user drawn region of interest shapes	Equivalent, both devices provide standard annotation tools
Reporting	Yes (PDF format)	Yes (HTML format)	Equivalent
JPEG lossless/lossy compression	Yes	Yes	Equivalent
Multi-monitor awareness	Yes	Yes	Equivalent
Image layout	Yes	Yes	Equivalent

Fundamentally, Syneris PACS is the same as the referenced predicate device in that it is a radiology image management system. As detailed above in the comparison table, most of their specifications and features are also the same and comparable. Syneris PACS and ONIS-PACS share a high degree of functional and technological overlap. Both serve the same clinical role within radiology workflows — managing, viewing, and measuring diagnostic images across a connected healthcare enterprise. Both devices are intended to be used by physicians or other licensed practitioners in healthcare institutions.

Syneris PACS also has some differences in technological characteristics when compared to its predicate device. The main differences are listed below:

- **Cloud/server-hosted architecture.** Syneris uses a cloud/server-hosted implementation, while ONIS-PACS uses Site Server and Organization Server components. This is an implementation difference in the storage, retrieval, and distribution architecture.
- **Browser-based viewing component.** ONIS-PACS includes WebONIS, an ActiveX component loaded into an HTML page and used with Microsoft Internet Explorer to provide functionality similar to ONIS Remote. Syneris PACS does not currently offer a WebONIS-equivalent browser-based component. Thus, the subject device uses a different access method and has a subset of the predicate's access modes. This difference does not raise different questions of safety or effectiveness.
- **Different remote-access implementation.** Both devices support distributed access to medical images, but the subject device implements this through the desktop Viewer and backend/server infrastructure rather than through a separate ONIS Remote component
- **Differences in direct import/export and DICOM services.** ONIS-PACS supports direct local/media import/export, DICOM Query/Retrieve, and DICOM Print Management. Syneris PACS does not support these functions and instead uses configured system-managed exchange through connected-system interfaces.
- **Named measurement presets.** Syneris PACS provides named orthopaedic and cardiac measurement presets that the predicate does not: Cobb angle, acetabular index, Sharp angle, centre-edge angle, Reimer index, Doppler velocity, Doppler time, Doppler trace, Doppler deceleration, and cardiac area and volume. Each preset applies an established published formula to landmarks placed manually by the user. The predicate provides the underlying angle, ratio and orthogonal constructions from which the orthopaedic indices are derived; the cardiac measurements are routinely performed on the acquiring ultrasound system at the time of acquisition. No image segmentation, landmark detection, automated analysis or interpretation is introduced, and the intended use is unchanged.
- **PET-CT fusion display.** Syneris PACS provides fusion display controls for PET-CT studies, comprising superimposition of the CT series over the PET series with adjustable fusion ratio, colour scheme, gamma, and fusion and

maximum levels. Fusion display is a presentation function that does not derive, quantify or interpret radiotracer uptake; neither device computes SUV or any other quantitative uptake metric.

7. Software Validation and Verification Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Device Software Functions".

The software verification and validation testing verified that the design requirements were successfully met. The Intended Use was successfully validated.

As the intended use, functionality, and performance of Syneris PACS and the predicate device are equivalent, the result of the performance testing is evidence that Syneris PACS performs in an equivalent manner to the ONIS-PACS.

8. Conclusion

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 device and the predicate device do not impact safety or effectiveness and do not raise new questions of safety or effectiveness. Syneris is equivalent in performance to existing legally marketed devices