June 25, 2026

Apryse Software Corp
Hilal Chami
Manager, Support and Implementation
2399 Blake St.
Denver, CO 80205-2186

Re: K260231
Trade/Device Name: MiPACS V5 (1.0.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 29, 2026
Received: May 29, 2026

Dear Hilal Chami:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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.	K260231

Please provide the device trade name(s).

MiPACS V5 (1.0.0.5)

Please provide your Indications for Use below.

MiPACS V5 is a software-only medical and dental DICOM image viewing system with integrated image acquisition functionality. MiPACS V5 is intended for use by trained healthcare professionals for the acquisition, viewing, manipulation, and management of medical and dental images in DICOM format. MiPACS V5 is not intended to replace primary diagnostic workstations and does not provide automated diagnosis, image interpretation, or clinical decision support.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K260231

General Summary of Submission / Executive Summary
Document Date: 2026-06-24
Device/Software Name: MiPACS V5
Version/Build: 1.0.0
Sponsor/Manufacturer: Apryse Software Corp
Submission Type: Traditional 510(k)
Product Code / Regulation: LLZ / 21 CFR 892.2050
Device Class: Class II
Predicate Device: MiPACS HTML5 Web Viewer (K212984)
Administrative Contact: Hilal Chami, Support, Integrations, & QA Manager, hilal.chami@apryse.com, 919-208-5312

1. Administrative Information

- **Common Name:** Dental Picture Archiving and Communication System (PACS)
- **Trade/Proprietary Name:** MiPACS V5
- **Classification Regulation:** 21 CFR 892.2050
- **Product Code: LLZ** (System, Image Processing, Radiological)
- **Classification Panel:** Radiology

MiPACS V5 is regulated as a Class II medical device under the Radiology panel and is subject to premarket notification requirements.

2. Device Description

MiPACS V5 is a software-only, web-based medical device designed for the viewing, acquisition, manipulation, and management of digital dental images in DICOM format. The device is intended for use by trained healthcare professionals in clinical environments and operates within customer-managed, on-premises infrastructure.

The system consists of the following primary functional components:

- Web-Based User Interface:
  - A browser-based interface providing image viewing, navigation, manipulation, and acquisition controls.
- Application Logic Layer:
  - Manages clinical workflows, user sessions, image handling, validation, and coordination of acquisition and storage functions.
- Image Acquisition Interface:

    - Interfaces with compatible, vendor-supported dental imaging devices to initiate image acquisition and receive image data. Image generation and hardware performance remain the responsibility of the acquisition device manufacturer.
- DICOM Communication Layer:
    - Supports DICOM and DICOM web standards (including QIDO-RS, WADO-RS, and STOW-RS) for image storage, retrieval, and transfer.
- Security and Access Control Layer:
    - Implements authentication, role-based authorization, session management, audit logging, and encrypted communication.

MiPACS V5 is deployed in a client–server model using standard web browsers on supported operating systems. No automated diagnosis, image analysis, or clinical decision-support functionality is provided.

3. Indications for Use

MiPACS V5 is a software-only medical and dental DICOM image viewing system with integrated image acquisition functionality. MiPACS V5 is intended for use by trained healthcare professionals for the acquisition, viewing, manipulation, and management of medical and dental images in DICOM format. MiPACS V5 is not intended to replace primary diagnostic workstations and does not provide automated diagnosis, image interpretation, or clinical decision support.

4. Predicate Device Comparison (Substantial Equivalence)

- **Primary Predicate:** MiPACS HTML5 Web Viewer (K212984)
- **Manufacturer:** MiPACS by Apryse
- **Intended Use:**
    - MiPACS V5 has the same intended use as the predicate device:
        - to support the acquisition, viewing, manipulation and management of digital dental images to aid clinical workflows.
- **Technological Characteristics:**
    - Both MiPACS V5 and the predicate device are web-based software systems that operate within clinical environments and utilize DICOM standards for image handling.
    - MiPACS V5 builds upon the predicate architecture by adding software-mediated image acquisition functionality via compatible acquisition devices. The fundamental viewing, navigation, storage, and security mechanisms remain consistent with the predicate.
- **Addressing Differences:**

- The added acquisition functionality was evaluated through software verification and validation testing, risk management activities, and cybersecurity assessment. These differences do not raise new questions of safety or effectiveness.

5. Summary of Non-Clinical Testing

Non-clinical testing was conducted to demonstrate that MiPACS V5 meets its specified requirements and performs safely and effectively for its intended use.

- **Software Verification & Validation:**
  - Software V&V activities were conducted in accordance with FDA guidance on software contained in medical devices (June 2023) at the Basic Documentation Level. Testing included unit, integration, and system-level verification of functional, performance, and security requirements.
- **Performance/Interoperability:**
  - Bench testing verified image rendering consistency, DICOM conformance, connectivity with external systems, database integrity, and end-to-end clinical workflows including image acquisition, storage, retrieval, and cache management.

6. Cybersecurity

Cybersecurity controls were implemented under a Secure Product Development Framework and documented within a Cybersecurity Management Plan consistent with FDA cybersecurity guidance. Activities included threat modeling, SBOM-based dependency analysis, security requirement verification, and risk-based vulnerability assessment.

7.Conclusion

All testing demonstrated that MiPACS V5 meets defined acceptance criteria and supports safe and effective clinical use. Based on the intended use, technological characteristics, and results of testing, **MiPACS V5 is substantially equivalent to the predicate device**, MiPACS HTML5 Web Viewer (K212984) and does not raise new questions of safety or effectiveness.

Hilal Chami

Jun 24 2026 Purpose: Document Approval

Authenticated via SMS 2FA

Hilal Chami

hilal.chami@apryse.com

Support, Integrations, & Quality Assurance Manager