October 22, 2025

Sirona Medical
Patrice Nedelec
Vice-President, Regulatory Affairs and Quality
171 2nd St.
San Francisco, California 94105

Re: K251030
Trade/Device Name: Sirona Advanced Imaging Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 14, 2025
Received: September 15, 2025

Dear Patrice Nedelec:

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.

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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)*
K251030

Device Name
Sirona Advanced Imaging Suite

Indications for Use *(Describe)*

Sirona Advanced Imaging Suite is a Medical Image Management and Processing System and consists of four PET (Positron Emission Tomography) viewing features which is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: PET and CT.

These features are as follows: a. PET-CT overlay/fusion, b. Measurement of Standardized Uptake Value on PET image series and generated PET-CT overlay/fusion, c. Maximum Intensity Reconstruction of PET image series, d. Multiplanar Reconstruction of PET image series and PET-CT overlay/ fusion.

Sirona Advanced Imaging Suite is intended to be used with the Sirona PACS (or MIMPS) Viewer.

The intended users of the PET Module are trained radiologists, medical professionals, or other healthcare providers within a healthcare organization.

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
Sirona Advanced Imaging Suite
K251030

Submitter: Sirona Medical

Contact Person: Patrice Jean Claude Nedelec - VP, RAQA Sirona Medical

Address:
171 2nd St.
Suite 600
San Francisco, CA 94105

Phone number: (727) 437-6804

Date prepared: 10/01/2025 (Additional information)

Name of Device: Sirona Advanced Imaging Suite

510(k) number: K251030
Product Code: LLZ (21 CFR 892.2050)
Classification Name: Medical Image Management and Processing System
Medical device Class: II

Name of Predicate Device: PIXMEO SARL Osirix MD

Predicate Device 510(k) number: K101342
Predicate Product code: LLZ (21 CFR 892.2050)
Classification Name : Medical Image Management and Processing System
Medical device Class: II

Device Description:
Sirona Advanced Imaging Suite is a software-based imaging solution designed to facilitate the review, analysis, and interpretation of positron emission tomography (PET) and computed tomography (CT) imaging studies. Intended to be used with the Sirona PACS (or MIMPS) Viewer, this module enables healthcare professionals, including radiologists and nuclear medicine physicians, to visualize, manipulate, and analyze multi-modality medical images for diagnostic and clinical decision-making.

Sirona Advanced Imaging Suite provides image fusion and co-registration capabilities, allowing users to overlay PET and CT images for combined anatomical and functional assessment. It supports multi-planar reconstructions (MPRs), maximum intensity projections (MIP), and standardized uptake value (SUV) calculations for metabolic activity assessment. The software is fully compatible with DICOM standards, ensuring seamless integration with imaging modalities and healthcare IT infrastructure.

Intended Use / Indications for Use
Sirona Advanced Imaging Suite is a Medical Image Management and Processing System and consists of four PET (Positron Emission Tomography) viewing features which is used

for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: PET and CT.

These features are as follows: a. PET-CT overlay/fusion, b. Measurement of Standardized Uptake Value on PET image series and generated PET-CT overlay/fusion, c. Maximum Intensity Reconstruction of PET image series, d. Multiplanar Reconstruction of PET image series and PET-CT overlay/ fusion.

Sirona Advanced Imaging Suite is intended to be used with the Sirona PACS (or MIMPS) Viewer.

The intended users of the Sirona Advanced Imaging Suite are trained radiologists, medical professionals, or other healthcare providers within a healthcare organization.

Comparison of Technological Characteristics

A table comparing the key features of the subject and predicate devices is provided below.

	SIRONA ADVANCED MEDICAL IMAGING	**PIXMEO SARL OsiriX MD**
Indications for Use	SIRONA ADVANCED IMAGING SUITE is a Medical Image Management and Processing System and consists of four PET (Positron Emission Tomography) viewing features which is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: PET and CT. These features are as follows: a. PET-CT overlay/fusion, b. Measurement of Standardized Uptake Value on PET image series and generated PET-CT overlay/fusion, c. Maximum Intensity Reconstruction of PET image series, d. Multiplanar Reconstruction of PET image series and PET-CT overlay/ fusion. Sirona Advanced Imaging Suite is intended to be used with the Sirona PACS (or MIMPS) viewer. The intended users of Sirona Advanced Imaging suite are trained radiologists, medical professionals, or other healthcare providers within a healthcare organization.	OsiriX MD is a software device intended for viewing of images acquired from CT, MR, CR, OR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post-process DICOM 'for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with the clinical application.
User Population	Licensed Radiologists and their clinical team	Licensed Radiologists and their clinical team
Technological Characteristics	SIRONA ADVANCED IMAGING SUITE is a cloud medical device platform enabling licensed Radiologists to review DICOM-compliant Medical images and report medical findings. It is not in contact with Patients nor does it control any life-sustaining devices. SIRONA ADVANCED IMAGING SUITE is compatible with Google Chrome version 134.0.6998.165 or	OsiriX MD is a software device that does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed. OsiriX MD software requires Mac OS X version 10.5 (Leopard) or higher. Although the software will work on any Macintosh platform, for optimal performance of some of the advanced image

	higher. A GPU with drivers that support OpenGL 3.0+ 16 GB of RAM is the minimum, 32GB is recommended, 64GB or more is preferred 250GB Hard Drive Internet download speed of at least 50Mbps Windows 64-bit Windows 10 or later Core i5 equivalent or above MacOS 64-bit macOS 15 Sequoia, macOS 14 Sonoma, macOS 13 Ventura, macOS 12 Monterey Intel Core i7, Xeon processor or faster Display 1920x1080 minimum resolution 60 Hz refresh rate minimum For Mammography viewing: Minimum 5MP display resolution Any number of monitors as desired	rendering tools and volume rendering of large image sets, it is recommended to use high end machines equipped with Intel processors (the faster the better). OsiriX MD also takes advantage of multiprocessor and multi-core machines to speed up rendering functions. Memory requirements will depend on the type and size of image sets you will be working with.
Components	**Viewer** features - SUV Standardized Uptake Value - MIPS Maximum Intensity Projection - MPR MultiPlanar Reformation - PET-CT overlay/fusion	- **Viewer** - Reporter - Worklist - Archive
Anatomical region of interest	All PET anatomical regions of interest	Scope of DICOM-compliant Medical Imaging
Findings Covered	All relevant medical imaging findings that stem from the review of the Radiologist.	All relevant medical imaging findings that stem from the review of the Radiologist.
Data acquisition protocol	DICOM-compliant medical imaging studies	DICOM-compliant medical imaging studies
View DICOM data	Yes	Yes
Preview images	Yes	Yes
Alteration of original image	No	No

Substantial equivalence discussion

Both devices offer clinical viewing capabilities to licensed and trained Clinical Radiology professionals in the purpose of issuing Patient Radiology reports.

Any difference solely relates to the technologies used for their similar purposes. However in Radiology practice, for the modalities in scope of Sirona Medical's device are equivalent to what its predicate offers, there is no difference noted. The intended uses are identical.

Likewise, this similarity and appropriate labeling provided in the user guide shared in this filing, validation protocols and results further indicate that the technological differences between the two devices do not affect the safety and effectiveness of Sirona Advanced Imaging Suite nor its intended use.

Bench Testing Summary

Bench testing evaluation was executed per procedure, according to the bench testing plan.

The conclusion is that the device meets its functional definition, meeting the objective of the bench testing phase.

Other non-clinical testing activities included Cybersecurity and Software verification and validation 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 Software Contained in Medical Devices."

Cybersecurity testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Performance (Clinical) Testing summary

Performance testing was executed per the Performance Plan to confirm Sirona Advanced Imaging Suite meets its intended use and user needs. Product specifications were tested and found to meet the requirements.

Conclusion from non-clinical and clinical tests

Bench Testing and Performance testing demonstrate that Sirona Advanced Imaging Suite is as safe and effective as the predicate device and thus is substantially equivalent to the predicate device.