July 6, 2026

Indigo Technologies
Andres Felipe Sanabria Diaz
Head of Product
Carrera 7 155 C 30 To E Of 3205 ED North Point
Bogota,
Colombia

Re: K261465
Trade/Device Name: Indira Cloud Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 2, 2026
Received: May 4, 2026

Dear Andres Felipe Sanabria Diaz:

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 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,

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)*
K261465

Device Name
Indira Cloud Viewer

Indications for Use *(Describe)*
The Indira Cloud Viewer is a visualization software intended to process and display image and associated data in a clinical setting.
The software displays images of different modalities and timepoints, and performs digital image processing, measurement, manipulation, quantification and communication. The Indira Cloud viewer is a web-based application and does not perform automated diagnosis and is not intended to replace clinical judgment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K261465

510(K) SUMMARY
INDIRA CLOUD VIEWER

Company's Name and Address	INDIGO TECHNOLOGIES SAS CARRERA 7 155 C 30 TO E OF 3205 ED NORTH POINT BOGOTA COLOMBIA
Contact Person	Andres Felipe Sanabria Diaz Head of Product +57 6013849900 calidad@indigo.tech
Date	02 May 2026
Device Trade name	INDIRA CLOUD VIEWER
Classification Name	System, image processing, radiological
Product Code	LLZ
Classification	21 CFR 892.2050
Predicate Device	Philips Medical Systems' AV Viewer (K250181)

Device description

Indira Cloud Viewer is a Software as a Medical Device (SaMD) developed for the visualization, processing, and manipulation of medical images in Digital Imaging and Communications in Medicine (DICOM) format.
The software enables authorized healthcare professionals to securely access and review medical imaging studies through a web-based, zero-footprint viewer without requiring local software installation. The system allows users to display and interact with DICOM images stored in secure cloud infrastructure.
Indira Cloud Viewer provides visualization and image manipulation tools that support clinical review of medical images by qualified healthcare professionals. The software does not perform automated diagnosis, computer-aided detection (CAD), or algorithmic image interpretation.

Indications for use:

The Indira Cloud Viewer is a visualization software intended to process and display image and associated data in a clinical setting.
The software displays images of different modalities and timepoints, and performs digital image processing, measurement, manipulation, quantification and communication. The Indira Cloud viewer is a web-based application and does not perform automated diagnosis and is not intended to replace clinical judgment

Verification and validation:

The verification and validation activities for the Indira Cloud Viewer were conducted in accordance with a comprehensive quality and regulatory framework aligned with internationally recognized standards.

Software lifecycle processes followed IEC 62304:2006 + AMD1:2015, including software development planning, requirements definition, architectural design, implementation, and systematic verification and validation. Traceability between requirements, risk controls, and test cases was maintained throughout the lifecycle.

Risk management activities were performed in accordance with ISO 14971:2019. Hazards, including those related to software functionality, usability, and cybersecurity, were identified and evaluated. Risk control measures were implemented and verified to ensure that residual risks are acceptable and that the benefit-risk profile supports safe and effective use.

Information security considerations were addressed in alignment with ISO/IEC 27001:2022, ensuring appropriate controls for data protection, access management, and system integrity within the cloud-based environment.

Cybersecurity principles were applied following AAMI TIR57 and AAMI TIR97, covering both premarket secure design and postmarket monitoring, vulnerability management, and incident response processes.

Usability engineering activities were conducted in accordance with IEC 62366-1:2015 + AMD1:2020 to minimize use-related risks. The user interface and workflows were evaluated to ensure safe and effective interaction by intended users in the intended use environment.

Verification activities included unit, integration, and system-level testing, as well as performance and regression testing. Validation activities confirmed that the software meets user needs and intended use in representative clinical scenarios.

Comparison feature	**Subject Device** Indira Cloud Viewer	**Predicate device** Philips Medical Systems' AV Viewer K250181	**Comparison**
Device Class	II	II	Equivalent
Classification panel	Radiology	Radiology	Equivalent
Product code	LLZ	LLZ	Equivalent
Regulatory Description	Medical image management and processing system	Medical image management and processing system	Equivalent
Regulation Number	892.2050	892.2050	Equivalent
Indications for Use	The Indira Cloud Viewer is a visualization software intended to process and display image and associated data in a clinical setting. The software displays images of different modalities and timepoints, and performs digital image processing, measurement, manipulation, quantification and communication. The Indira Cloud Viewer is not to be used for mammography. The Indira Cloud viewer is a web-based application and does not perform automated diagnosis and is not intended to replace clinical judgment"	The AV Viewer is an advanced visualization software intended to process and display image and associated data in a clinical setting. The software displays images of different modalities and timepoints, and performs digital image processing, measurement, manipulation, quantification and communication. The AV Viewer is not to be used for mammography.	Equivalent
Clinical characteristics			
Intended users	Trained professionals: radiologists and radiology technicians	Trained professionals, including but not limited to, physicians and medical technicians	Similar
Supported imaging modalities	CT, CBCT –CT format, Spectral CT, MR, EMR, NM, PET, SPECT, US, XA, DX, CR, RF, ECG.	CT, CBCT –CT format, Spectral CT, MR, EMR, NM, PET, SPECT, US, XA, DX, CR, RF, ECG.	Equivalent
Technological features			
2D and 3D viewing capabilities	Yes	Yes	Equivalent

2D measurements (line, ROI, angle etc.)	Yes	Yes	Equivalent
3D Segmentation on CT and MR datasets	Yes	Yes	Equivalent
Cine View – sequence of images as a movie	Yes	Yes	Equivalent
Finding dashboard	Yes	Yes	Equivalent
Reporting	No	Yes	Different
Exporting reports and derived data	Yes	Yes	Equivalent
Cloud based application	Yes	It has the possibility of a cloud base application	Similar

Substantial Equivalence

The Indira Cloud Viewer has the same intended use as the predicate device from Philips Medical Systems (AV Viewer, K250181). Both are medical image visualization software intended for use by trained healthcare professionals to process, display, and analyze multi-modality medical images in clinical environments, without performing automated diagnosis or replacing clinical judgment.

Technologically, both devices share the same core functionalities, including 2D/3D visualization, image manipulation, measurement, segmentation, and communication tools. The subject device is cloud-based, while the predicate can also be deployed in a cloud environment; this difference relates only to deployment and does not impact performance or safety. The absence of reporting functionality in the subject device does not affect the intended use and does not introduce new risks. All identified differences have been assessed through risk management and supported by verification and validation (V&V) activities.

Clinically, both devices are used by similar user groups (e.g., radiologists and physicians), support the same imaging modalities (CT, MR, PET, SPECT, ultrasound, and X-ray), and are integrated into comparable clinical workflows. There are no differences that impact clinical performance, safety, or effectiveness.

Conclusion on Substantial Equivalence:

The Indira Cloud Viewer is substantially equivalent to the predicate device from Philips Medical Systems, as it has the same intended use, similar technological characteristics, and no differences that raise new questions of safety or effectiveness.