July 23, 2026

Candelis, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K262143
Trade/Device Name: ImageGrid StreamVue
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 25, 2026
Received: June 25, 2026

Dear Prithul Bom:

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,

for

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.	K262143

Please provide the device trade name(s).

ImageGrid StreamVue

Please provide your Indications for Use below.

ImageGrid StreamVue is a device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, and displayed within the system or across computer networks at distributed locations. Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians as an adjunctive to standard radiology practices for diagnosis. Typical users of this system are trained professional physicians, radiologists, nurses, medical technicians, and assistants.

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)

510(k) #: **K262143**

510(k) Summary

Prepared on: 2026-06-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Candelis, Inc.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ImageGrid StreamVue
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K092949	ImageGrid Radiology Viewer System	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

ImageGrid StreamVue is a software-only medical device that functions as a diagnostic image viewing application within the ImageGrid product family. The device provides authorized users with the ability to view medical images that are stored and managed by upstream image management systems.

ImageGrid StreamVue is a modified version of the ImageGrid Radiology Viewer System previously cleared under FDA 510(k) number K092949, with no changes to intended use or indications for use.

The subject device uses image streaming technology to deliver medical images to the end user for viewing. Image rendering and interaction occur without requiring full local storage of the image dataset on the client system. This change replaces the prior method of locally loading complete image data while maintaining the same user-facing diagnostic viewing functionality.

The device is intended to be used as part of a medical image management workflow and does not acquire medical images directly. ImageGrid StreamVue does not perform image acquisition, image reconstruction, or image analysis. No computer-aided detection,

computer-aided diagnosis, or artificial intelligence algorithms are introduced or modified.
ImageGrid StreamVue is implemented as a software application that interfaces with existing ImageGrid infrastructure to request, stream, and display medical images. The device supports interactive image viewing functions consistent with the previously cleared device. The introduction of streaming technology represents a change in data delivery and rendering architecture only. There are no changes to the device's intended use, indications for use, clinical functionality, or diagnostic purpose.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

ImageGrid StreamVue is a device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, and displayed within the system or across computer networks at distributed locations. Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians as an adjunctive to standard radiology practices for diagnosis. Typical users of this system are trained professional physicians, radiologists, nurses, medical technicians, and assistants.

Indications for Use Comparison 21 CFR 807.92(a)(5)

There are no changes to the device's indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

ImageGrid StreamVue and the predicate device, ImageGrid Radiology Viewer System (K092949), are both software-only medical image viewing systems classified under 21 CFR 892.2050, Product Code LLZ. Both devices are intended to receive, retrieve, and display medical images from an upstream PACS for diagnostic viewing by trained healthcare professionals. Both devices support standard diagnostic image viewing workflows and use the same fundamental scientific technology of medical image management and display.

The primary technological difference between ImageGrid StreamVue and the predicate device is the image delivery architecture. The predicate device downloads image data to the client workstation and performs local image decoding. ImageGrid StreamVue performs image rendering on the server side and streams rendered viewport images to the client application for display and interaction. This architecture eliminates storage or persistence of DICOM image objects on the client system.

This difference is limited to the method of image delivery. It does not change the device's intended use, indications for use, user population, diagnostic functionality, supported image viewing purpose, or fundamental scientific technology. The subject device remains a software-based medical image viewing system used by trained healthcare professionals as an adjunct to standard radiology practices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical performance testing was conducted to support a determination of substantial equivalence between ImageGrid StreamVue and the predicate device, ImageGrid Radiology Viewer System (K092949).

Testing included comparative diagnostic image quality evaluation, system-level software verification and validation, regression testing, and validation activities. Comparative image quality testing was performed using representative DICOM studies across CR, CT, MR, US, MG, and fluoroscopy. The reviewer evaluated diagnostic quality, artifacts, and functional limitations. The results showed diagnostic image quality for all reviewed modalities, with comparable image quality for mammography, ultrasound, fluoroscopy, CT, and MR, and superior/faster performance for X-ray/CR.

System-level software testing evaluated retrieval of medical images from the upstream PACS, server-side image rendering and streaming to the client, display and interaction with streamed medical images, standard diagnostic viewing functions, and system behavior under expected operating conditions. All planned system-level test cases passed, and any observations or anomalies were evaluated and determined not to impact safety or effectiveness.

Software verification and validation activities included requirements verification testing, system-level testing, image quality testing, and regression testing. These activities were traceable to software requirements and identified risks through the Traceability Matrix.

Testing and risk management activities reference the FDA-recognized standards declared in this submission, including NEMA PS 3.1–3.20 2024e (DICOM), IEC 62304, IEC 60812, and ISO 14971.

Not Applicable