December 4, 2020

Nucleus Health, LLC
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K203249
Trade/Device Name: Nucleus.io
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 3, 2020
Received: November 4, 2020

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203249

Device Name
Nucleus.io

Indications for Use *(Describe)*

Nucleus.io is a software-based image management solution and PACS to be used by radiologists, other medical personnel and patients. Nucleus.io is comprised of software modules that provide image receipt, diagnostic viewing, storage, distribution, enhancement, sharing, manipulation, and networking of medical 2D/3D images at distributed locations.
All modules of Nucleus.io are web-based and can operate on off-the-shelf hardware, as needed. Nucleus.io consists of the following primary components: Nucleus.io Viewer (dX) with image streaming technology for use by medical professionals for diagnostic and clinical image review-Nucleus.io Image Exchange (iX) for image acceptance, transfer, and sharing with hospitals/clinics as well as between facilities , Nucleus.io Infinite Store (iS) for secure cloud-based image storage and management through HIPAA compliant encryption-Nucleus.io PACS for radiology workflow and worklist features when used in conjunction with Nucleus.io dX and, optionally , Nucleus.io iS-and Nucleus.io PaaS, which provides a vendor-neutral Class I platform that can be incorporated as a component of other devices.

Nucleus.io interfaces with health information systems (HIS) using industry-standard image transfer and data exchange protocols-such as DICOM, HL7, and HTML-through web-based networked gateways and local and wide area networks. Nucleus.io is compatible with modalities including Computed Tomography (CT), Magnetic Resonance Imaging (MR), Ultrasound (US), Computed Radiography (CR), Digital Radiography (DX), Nuclear Medicine (NM), Positron Emission Tomography (PET), and X-Ray Angiography (XA). When appropriate, Nucleus.io provides and installs software and, optionally, off-the-shelf server hardware at client facilities to facilitate secure, web-based connections for image transmission to and from hospital central servers via the Internet. Additionally, industry standard HTTPS, VPNs, and other encryption methodologies are utilized to allow for optimal, secure, rapid streaming of images. Lossless image compression and encryption adhere to standard industry protocols. Nucleus.io can be used as a full-featured PACS or as an independent viewer in clinical settings.

Although the web and thin client technologies allow the software to be run on a variety of hardware platforms, for diagnostic purposes the user must make sure that the display hardware used for reading the images complies with state of- the-art diagnostic requirements and currently valid laws.
Only DICOM for presentation images can be used on an FDA approved monitor for mammography for primary image diagnosis.
Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.
Not for diagnostic use on mobile devices.

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.

1 Introduction and Administrative Information

This 510(k) Summary provides a high-level summary of the contents of the Nucleus.io Premarket Notification (510(k)), including a comparison of Nucleus.io to existing legally marketed medical devices.

This Premarket Notification (510(k)) Summary contains no confidential or trade secret information. For additional information, please contact the Establishment's contact listed below.

This summary was prepared on July 09, 2020.

1.1 Submitter

Submitter	NucleusHealth, LLC
Submitter Address	13280 Evening Creek Dr. S San Diego CA, 92128
Submitter Phone	(858) 251-3400
Submitter Website	www.nucleushealth.io
Establishment Number	3008008144
Establishment Contact	Zachary Wright
Contact Title	Manager, Regulatory Affairs and Quality
Contact Phone	(858) 251-3400
Contact Fax	(858) 546-3900
Contact Email	zwright@nucleushealth.io

1.2 Device Identification

Proprietary Name(s):	Nucleus.io
Classification Name:	Picture Archiving & Communications System (PACS)
Common / Usual Name:	Medical Image Processing Software

1.3 Device Classification

Nucleus.io is product code LLZ, which is a Class II medical device per 21 CFR 892.2050.

Similarly, classification of Nucleus.io per IEC 62304 Edition 1.0 2015-06 was assigned by assessing the highest risk classification first:

- Death or serious injury is not possible. Thus, the device is not Class C.

- Non-serious injury is possible. Thus, the device is Class B.
- As some injury or damage to health is possible, the device is not Class A.

1.4 Related Previous Submissions

Previously cleared as “Nucleus Image Management System” in the United States as a Class II medical device under 510(K) K171130.

1.5 Predicate Device Identification

Proprietary Name(s):	Visage PACS/CS
510(k) File:	K082269
Classification Name:	Picture Archiving & Communications System (PACS)

No reference devices were used in this submission.

2 Device Description and Intended Use

2.1 Device Description

Nucleus.io is a PACS which, when integrated with standard off-the-shelf hardware/software, acts similarly to its predicate device and other industry standard PACS systems.

The Nucleus System has the following primary features and functions:

- Zero-footprint HTML5 medical image acceptance (upload) and transfer of medical images between facilities.
- Easy, real-time access to images for all participants in the healthcare process, including radiologists, imaging
- technicians, workflow coordinators, physicians, nurses, and other patient care facilitators.
- High-speed, zero-footprint diagnostic review of medical images using industry-standard tools for manipulation, annotation, measurement, and comparison.
- Simultaneous information review with multiple parties, including radiologists and coordinators.
- Sharing of medical images between healthcare providers, facilities, and patients.
- Encrypted transmission of medical images through secured wired and wireless networks.
- Encrypted storage of medical images.
- Organization and matching of multiple medical images based on patient name, medical record number, facility, etc.
- Quality assurance review of studies by coordinators and preparation of information for study interpretation by radiologists.
- Notification of care coordinators that studies need to be transferred to client systems.
- HIPAA-compliant data management and LDAP security integration with external systems
- Management of users, roles, permissions, and organization accounts
- Configuration of image acceptance (upload) and transfer settings

The Nucleus.io System consists of the following primary components:

Nucleus.io Image Exchange (iX)™

- Exam acceptance (upload), transfer, sharing, and management

Nucleus.io Viewer (dX)™

- Zero-footprint streaming viewer suitable for diagnostic image review of all modalities

Nucleus.io Infinite Store (iS)™ (formerly Image Store)

- Image storage and archiving

Nucleus.io PACS™

- Radiology workflow and worklist features

Nucleus PaaS

- Vendor-neutral Class I platform that can be incorporated as a component of other devices

Note: When Nucleus is used as a PaaS, the resulting device carries its own intended use, and must be filed as a separate medical device which uses Nucleus as a component, as appropriate. PaaS is mentioned here only to assist in understanding the features present in Nucleus IMS.

The graphic below provides a high-level architectural view of how the product interacts with external users and systems:

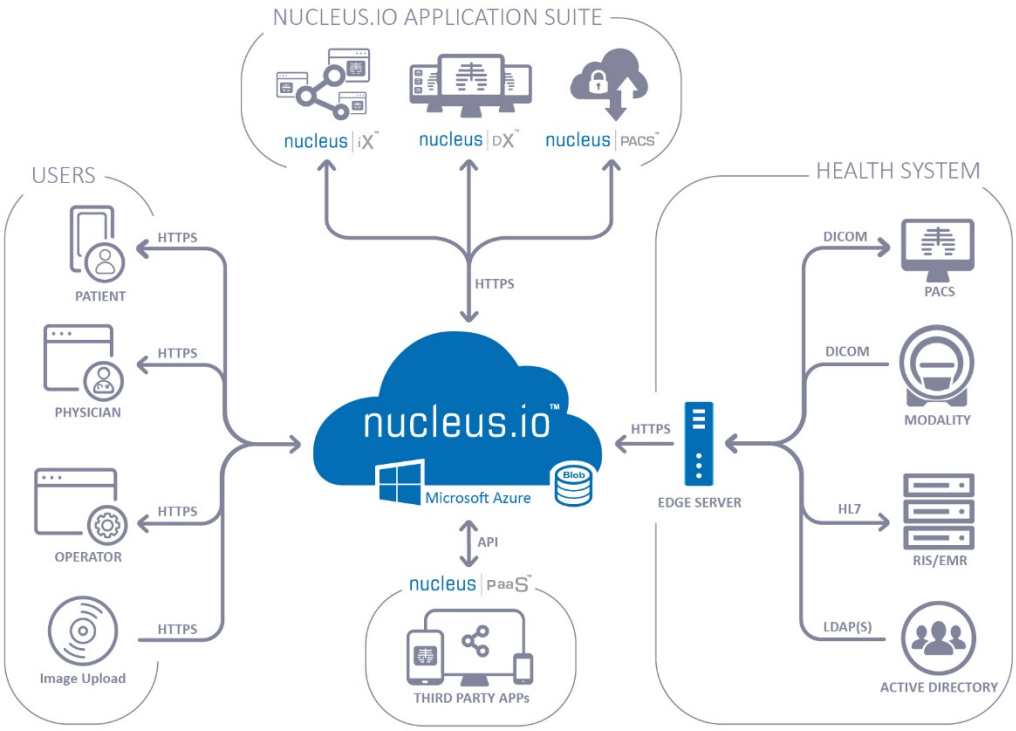

Figure 1. Marketing Description, Nucleus.io architecture

The following images provide visual examples of features used in the most common user workflows. Many additional features are available, and are fully described in the User Manuals, discussed in the Proposed Labeling (Section D of the submission).

The interface depicted in Figure 2, below, is displayed when the user logs in. This interface provides access to the most common features used by hospital staff and Radiologists.

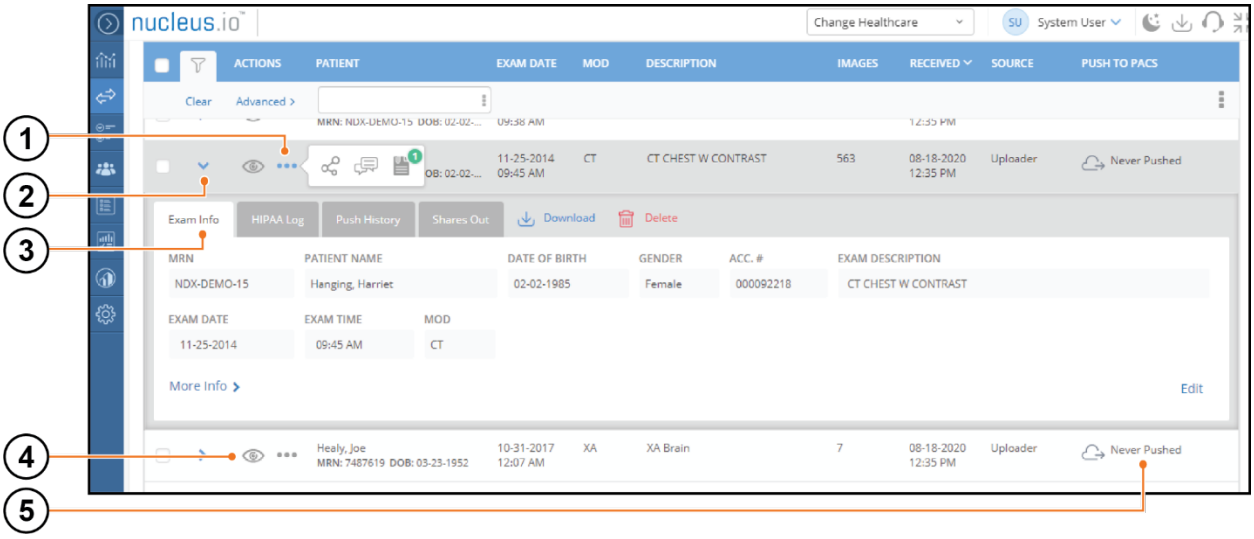

Figure 2. Nucleus.io Primary User Interface

Item	Description
1	By selecting the ellipsis icon (…) on an exam line item, an authorized user can share the exam to another Organization, to the patient, to another professional, or directly to an email address.
2	Detailed exam information can be viewed by selecting the arrow icon (>) on an exam line item.
3	From this expanded view, an authorized user can edit, download or delete the exam. Exam history, including all access to Personal Health Information (PHI) is also available.
4	By selecting the eye icon ( ), an authorized user can view the exam. See Figure 4 for the interface displayed when viewing exams.
5	By selecting the button in the Push to PACS column, an authorized user can send the exam to a configured external PACS system. The icon displays the current push status for the exam (e.g., Never Pushed, In Progress, Complete).

Figure 3 depicts the clinical exam viewer available from the main user interface. This viewer meets the needs of most system users. The “Dx” viewer, also available within Nucleus.io, has additional image manipulation and diagnostic features, but shares a similar interface.

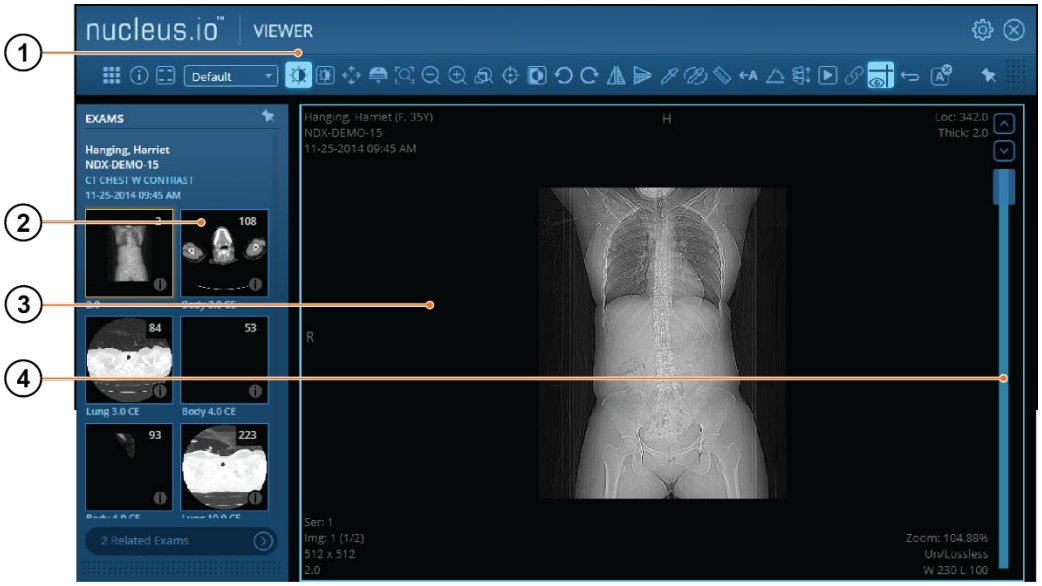

Figure 3. Nucleus.io Clinical Viewer User Interface

Item	Description
1	Icons in the tool bar at the top of the screen allow the user to work with the images on screen. This includes features such as changing contrast, rotating, zoom, measuring, and playback. The user may also configure the layout of the viewer to determine settings such as how many series/images can be displayed at once.
2	The windows at the left show the exam series available, as specified when the exam was performed and compiled into a DICOM-compatible format.
3	The main window shows the selected image series (per Item 2) and may be configured to show more than one image at a time.
4	The scroll bar serves multiple functions, including the ability to scroll and a “loading” bar to show download (or “streaming” progress of the displays series. In this example, the blue portion of the scroll bar indicates images which have loaded, and the darker portion of the scroll bar indicates images which are still loading.

2.2 Intended Use/Indications for Use

Nucleus.io is a software-based image management solution and PACS to be used by radiologists, other medical personnel and patients. Nucleus.io is comprised of software modules that provide image receipt, diagnostic viewing, storage, distribution, enhancement, sharing, manipulation, and networking of medical 2D/3D images at distributed locations.

All modules of Nucleus.io are web-based and can operate on off-the-shelf hardware, as needed. Nucleus.io consists of the following primary components: Nucleus.io Viewer (dX) with image streaming technology for use by medical professionals for diagnostic and clinical image review—Nucleus.io Image Exchange (iX) for image acceptance, transfer, and sharing with hospitals/clinics as well as between facilities, Nucleus.io Infinite Store (iS) for secure cloud-

based image storage and management through HIPAA compliant encryption—Nucleus.io PACS for radiology workflow and worklist features when used in conjunction with Nucleus.io dX and, optionally, Nucleus.io iS—and Nucleus.io PaaS, which provides a vendor-neutral Class I platform that can be incorporated as a component of other devices.

Nucleus.io interfaces with health information systems (HIS) using industry-standard image transfer and data exchange protocols—such as DICOM, HL7, and HTML—through web-based networked gateways and local and wide area networks. Nucleus.io is compatible with modalities including Computed Tomography (CT), Magnetic Resonance Imaging (MR), Ultrasound (US), Computed Radiography (CR), Digital Radiography (DX), Nuclear Medicine (NM), Positron Emission Tomography (PET), and X-Ray Angiography (XA). When appropriate Nucleus.io provides and installs software and, optionally, off-the-shelf server hardware at client facilities to facilitate secure, web-based connections for image transmission to and from hospital central servers via the Internet. Additionally, industry standard HTTPS, VPNs, and other encryption methodologies are utilized to allow for optimal, secure, rapid streaming of images. Lossless image compression and encryption adhere to standard industry protocols. Nucleus.io can be used as a full-featured PACS or as an independent viewer in clinical settings.

Although the web and thin client technologies allow the software to be run on a variety of hardware platforms, for diagnostic purposes the user must make sure that the display hardware used for reading the images complies with state of- the-art diagnostic requirements and currently valid laws.

Only DICOM for presentation images can be used on an FDA approved monitor for mammography for primary image diagnosis.

Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.

Not for diagnostic use on mobile devices.

3 Predicate Device Comparison

3.1 Context for Predicate Device Selection

Nucleus.io was previously cleared under 510(k) K171130 as Nucleus Image Management System, contraindicated for diagnosis of mammography. This submission seeks to remove that contraindication now that features are available to support this indication.
Within the K171130 submission, StatPACS (K092134) was identified as a predicate device. StatPACS is a client-server-based PACS which is contraindicated for diagnosis of mammography.

Within the StatPACS (K092134) submission, Visage PACS/CS (K082269) was identified as a predicate device. Visage PACS/CS is also a client-server-based PACS but includes an indication for diagnosis of mammography. A key difference between StatPACS and Visage PACS/CS is that Visage PACS/CS is indicated for diagnosing mammography.
Note: This difference was not noted in K092134 as the StatPACS indications for use did not include diagnosis of mammography.

In conclusion, the predicate device selected for this submission is Visage PACS/CS (K082269) as the technological differences have previously been shown to not introduce additional safety

or effectiveness concerns; and because the features provided for diagnosis of mammography are similar to those provided in Nucleus.io.

3.2 Device Comparison

The features in Nucleus.io related to diagnosis of mammography were developed based on the principle features and operations within its predicate device, Visage PACS/CS (K082269). There are two primary differences between the products:

1) Nucleus.io is modular, allowing the user to gain access to either minimal features needed in smaller/niche environments, or scale to a full PACS.
2) Nucleus.io uses cloud architecture to replace traditional server hosting, and web browser technology to replace thick client applications, in order to increase the availability of the system for medical professionals in remote locations and to access to health records for patients.

Both Visage PACS/CS and Nucleus.io run on off-the-shelf PC hardware utilizing industry-standard operating systems and interfaces to all hospital modalities.

Both products support non-compressed, lossless compressed, and lossy compressed image/data transmission. The default mode of operation is non-compressed, lossless compression. Changes to the standards which may affect the compression coding will be evaluated to worth and merit and if adopted, validated and verified to show compliance to the standard. This method fully preserves image data integrity but allows reduced transmission times and reduced storage requirements.

As PACS (Picture Archiving and Communications Systems) are multi-site/location systems, both Visage PACS/CS and Nucleus.io support various industry standard connectivity including, but not limited to LAN/WAN/VPN/Wireless technology, which enables data/images to be transmitted with speed and accuracy. Nucleus.io has adopted image transfer using streaming technology, which enables the medical professional to obtain the images in a fast, safe and efficient manner as compared to the traditional file download features used in Visage PACS/CS.

3.2.1 Indications for Use Comparison

The intended uses/indications for use of the devices, shown below, include comparable purposes. Differences include:

- Patients are specifically mentioned as users in the Nucleus.io documentation, as patients may access their records for non-diagnostic purposes similar to the common practice of a physician providing the patient a CD-ROM.
- Non-exhaustive lists of modalities compatible with the devices are provided; and different modalities were selected to include in the list by each company. However, all modalities listed for each can be found in the DICOM Conformance Statements for each device; these differences are limited to the wording used and specific items to be included in the non-exhaustive list. Both DICOM Conformance statements are provided in Section C of this submission. In particular, the following Classes confirm their equivalence with respect to the Intended Uses:
    - 1.2.840.10008.5.1.4.1.1.3.1
    - 1.2.840.10008.5.1.4.1.1.6.1

  - 1.2.840.10008.5.1.4.1.1.1
  - 1.2.840.10008.5.1.4.1.1.20
  - 1.2.840.10008.5.1.4.1.1.128
  - 1.2.840.10008.5.1.4.1.1.12.1
- Two warnings are included at the bottom of the Visage PACS/CS intended use which are not explicitly mentioned in the Nucleus.io intended use. Nucleus.io has implemented these warnings differently in documentation, including these within the User Manuals.

Subject Device	Comparable Device
Nucleus.io (NA – Proposed Device)	Visage PACS/CS (K082269)
Nucleus.io is a software-based image management solution and PACS to be used by radiologists, other medical personnel, and patients. Nucleus.io is comprised of software modules that provide image receipt, diagnostic viewing, storage, distribution, enhancement, sharing, manipulation, and networking of medical 2D/3D images at distributed locations. All modules of Nucleus.io are web-based and can operate on off-the shelf hardware, as needed. The Nucleus.io IMS consists of the following primary components: Nucleus.io Viewer (dX) with image streaming technology for use by medical professionals for diagnostic and clinical image review—Nucleus.io Image Exchange (iX) for image acceptance, transfer, and sharing with hospitals/clinics as well as between facilities—Nucleus.io Infinite Store (iS) for secure cloud based image storage and management through HIPAA compliant encryption—Nucleus.io PACS for radiology workflow and worklist features when used in conjunction with Nucleus.io dX and, optionally, Nucleus.io iS—and Nucleus.io PaaS, which provides a vendor-neutral Class I platform that can be incorporated as a component of other devices. Nucleus.io interfaces with health information systems (HIS) using industry standard image transfer and data exchange protocols—such as DICOM, HL7, and HTML—through web-based networked gateways and local and wide area networks. Nucleus.io is compatible with modalities including, but not limited to: Computed Tomography (CT), Magnetic Resonance Imaging (MR), Ultrasound (US), Computed Radiography (CR), Digital Radiography (DX), Nuclear Medicine (NM), Positron Emission Tomography (PT), and X-Ray Angiography (XA). When appropriate,	Visage PACS/CS is a system for distributing, viewing, processing, and archiving medical images within and outside health care environments. The Visage PACS/CS server receives images data in DICOM format via the hospital network. This provides universal connections to archives, modalities, and workstations. The supported modalities are listed in the DICOM Conformance Statement. Besides general image interpretation and processing tools, Visage PACS/CS provides specific tool sets for several clinical applications, including: - CT/MR angiography, e.g., for vascular analysis and stent planning - Cardiac analysis, including calcium scoring and functional assessment of cardiac CT data - Neuroradiology, including CT and MR brain perfusion analysis Visage PACS/CS is to be used only by trained and instructed health care professionals. It can support physicians and/or their medical staff in providing their own diagnosis for medical cases. The final decision regarding diagnoses, however, resides with the doctors and/or their medical staff in their own area of responsibility. Although the web and thin client technologies allow the software to be run on a variety of hardware platforms, for diagnostic purposes the user must make sure that the display hardware used for reading the images complies with state-of-the-art diagnostic requirements and currently valid laws.

Subject Device	Comparable Device
Nucleus.io provides and installs software and, optionally, off-the-shelf server hardware at client facilities to facilitate secure, web-based connections for image transmission to and from hospital central servers via the Internet. Additionally, industry standard HTTPS, VPNs, and other methodologies are utilized to allow for optimal, secure, rapid streaming of images. Lossless image compression and encryption adhere to standard industry protocols. Nucleus.io can be used as a full-featured PACS or as an independent viewer in clinical settings.	Only DICOM for presentation images can be used on an FDA approved monitor for mammography for primary image diagnosis. Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.

3.2.2 Tabular Comparison of Features

The table below provides a side-by-side comparison of key features.

Feature/Function	Subject Device	Comparable Device
Product Name	Nucleus.io	Visage PACS/CS
510(k) Number	N/A – Proposed Device	K082269 Primary Predicate Device
Manufacturer	Nucleus Health, LLC	Visage Imaging, Inc.
Web Site	www.nucleushealth.io	www.visageimaging.com
Overview of devices	PACS/clinical viewing/image sharing/storage/long term archiving	PACS/clinical viewing/image sharing/storage/long term archiving
User Types	Hospital Administrative Staff, Technicians, Radiologists, Patients	Hospital Administrative Staff, Technicians, Radiologists, Patients
Supports DICOM image transfer	Yes	Yes
Software based	Yes (moderate concern)	Yes (moderate concern)
LAN/WAN support	Yes	Yes

Feature/Function	Subject Device	Comparable Device
HTML/Web based image transfer	Yes	Yes
Client Hardware	Zero-footprint (browser) minimum	Thin Client minimum
Image streaming	Yes	No
Secure image sharing to outside locations	Yes	Yes
Dual monitor support	Yes	Yes
Diagnostic/Clinical viewing	Yes	Yes
Off the shelf hardware	Yes	Yes
JPEG/industry standard lossy/lossless compression	Yes	Yes
Zoom/panning features	Yes	Yes
Image flip/rotate capability	Yes	Yes
Text annotation	Yes	Yes
Statistical reporting	Yes	Yes
ROI	Yes	Yes
Window level by region	Yes	Yes
HIS/RIS connectivity	Yes	Yes
Off-site viewing (including teleradiology)	Yes	Yes
Fax support	Yes	Yes
Scalable platform	Yes	Yes
HIPAA compliant (encryption)	Yes	Yes
HL-7 integration	Yes	Yes
LDAP security integration	Yes	Yes
Archiving to cloud based or network servers	Yes	Yes

Feature/Function	Subject Device	Comparable Device
General admin features (assign, relate studies, etc.)	Yes	Yes
Secure log in	Yes	Yes
Support for Mammography	Yes	Yes

Features specifically implemented for viewing mammography studies are shown below.

Feature/Function	Subject Device	Comparable Device
Product Name	Nucleus.io	Visage PACS/CS
Quadrant Navigation	Yes	Yes
Next/Previous Prior Exam	Yes	Yes
Change between 2D, Projection, and 3D (Tomo) Display	Yes	Yes

4 Performance Data

4.1 Risk Management

The Nucleus.io Hazard and Risk Management Plan, Analysis, and Report was performed to determine and evaluate all potential health and safety hazards associated with use of the platform. All foreseeable system hazards, effects, and causes have been evaluated to determine necessary and appropriate risk mitigations. Verification and validation, risk mitigation traceability, and design review, have been performed to ensure effective implementation of the stated risk mitigations.

4.2 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." The software for this device was classified as a Moderate Level of Concern software medical device, due to the low potential for injury possible in the event of software/hardware failure, both directly and indirectly. Per the Hazard and Risk Management Plan, Analysis, and Report, no pre-mitigation items are life-threatening, and all have been mitigated to "minor" (results in temporary injury or impairment not requiring professional medical intervention) or lower.

Verification and Validation Protocols have been executed to ensure adequate testing of all defined product design requirements and specifications. Verification and Validation Test Reports have been created to evaluate the acceptability of test results and product module / product release preparedness. All applicable design and development and verification and

validation activities and records have been completed to ensure safety and effectiveness of the final Nucleus.io platform

All technological characteristics and performance requirements identified in the Predicate Device Comparison have been tested to ensure success of the design implementation. There are no new or different issues of safety or effectiveness introduced by the stated design change. Risk Management and Verification and Validation activities confirm that Nucleus.io meets its specifications.

5 Conclusions

The comparison above in tabular format enables one to see how Nucleus.io compares in intent and usage to its predicate device, Visage PACS/CS. Specifically, all features identified for diagnosing mammography by Visage PACS/CS are also available within Nucleus.io. Therefore, Nucleus.io raises no new issues of safety or effectiveness from its predicate device.