November 12, 2024

Change Healthcare Canada Company
Alona Golik
VP, Quality Assurance and Regulatory Affairs
10711 Cambie Road
Richmond, BC V6X3G5
Canada

Re: K241981
Trade/Device Name: Change Healthcare Stratus Imaging PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 17, 2024
Received: October 17, 2024

Dear Alona Golik:

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,

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.

Submission Number *(if known)*

K241981

Device Name

Change Healthcare Stratus Imaging PACS

Indications for Use *(Describe)*

Change Healthcare Stratus Imaging PACS is a software-based medical image management and processing system intended to process and display medical images for the purposes of diagnostic viewing and interpretation by qualified and trained healthcare professionals, including, but not restricted to, radiologists and non-radiology physicians.

The Diagnostic Viewer of Change Healthcare Stratus Imaging PACS provides medical image post-processing functions such as image manipulation and enhancement that are intended for use in the clinical image review and analysis of medical images acquired through DICOM-compliant imaging devices or IT interfaces.

Change Healthcare Stratus Imaging PACS can be used as a full-featured medical image management and processing system or as an independent viewer in clinical settings.

Only uncompressed or non-lossy compressed DICOM images can be used for primary image diagnosis and interpretation for mammography using monitors intended for mammography display and cleared by the regulatory authority in your region or jurisdiction.

Change Healthcare Stratus Imaging PACS is not intended 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.

510(k) #: K241981

510(k) Summary

Prepared on: 2024-10-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Change Healthcare Canada Company
Applicant Address	10711 Cambie Road Richmond BC V6X3G5 Canada
Applicant Contact Telephone	972-52-4084942
Applicant Contact	Mrs. Alona Golik
Applicant Contact Email	ei.regulatory@optum.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Change Healthcare Stratus Imaging PACS
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
K203249	Change Healthcare Stratus Imaging PACS; Nucleus.io	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

Change Healthcare Stratus Imaging PACS is a software-based medical image management and processing system designed to perform the necessary functions required for diagnosis and interpretation of medical images and other related medical information. It is intended to be used by qualified and trained radiologists and non-radiology physicians for the purpose of assisting in diagnosis and interpretation of medical images.

Change Healthcare Stratus Imaging PACS provides users with a zero-footprint, browser-based diagnostic viewer capable of directly displaying diagnostic quality DICOM standard images, reports and discrete data information acquired by various data sources. The diagnostic viewer provides users with tools and features, including measurement, annotations, comparison, and digital processing of medical images, such as image manipulation, enhancement, and 3D/4D visualization.

Change Healthcare Stratus Imaging PACS also provides PACS functionality, such as storage, import, sharing, retrieval, and display, that supports the day-to-day operations of qualified and trained healthcare professionals, such as technologists and PACS administrators.

Change Healthcare Stratus Imaging PACS uses a cloud-based architecture offering zero-footprint deployment in hospitals, clinics imaging centers and other healthcare facilities. Authorized users from both clinical facilities and remote locations can directly access Change Healthcare Stratus Imaging PACS.

Change Healthcare Stratus Imaging PACS operates on approved web browsers running on commercially available hardware that meets approved specifications.

Change Healthcare Stratus Imaging PACS is designed to integrate with third party, off-the-shelf software through Application Programming Interfaces (APIs) and supported standards (for example, HL7, DICOM) to allow connectivity with systems used in the

clinical environment such as reporting tools, EMRs, and advanced visualization tools.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Change Healthcare Stratus Imaging PACS is a software-based medical image management and processing system intended to process and display medical images for the purposes of diagnostic viewing and interpretation by qualified and trained healthcare professionals, including, but not restricted to, radiologists and non-radiology physicians.

The Diagnostic Viewer of Change Healthcare Stratus Imaging PACS provides medical image post-processing functions such as image manipulation and enhancement that are intended for use in the clinical image review and analysis of medical images acquired through DICOM-compliant imaging devices or IT interfaces.

Change Healthcare Stratus Imaging PACS can be used as a full-featured medical image management and processing system or as an independent viewer in clinical settings.

Only uncompressed or non-lossy compressed DICOM images can be used for primary image diagnosis and interpretation for mammography using monitors intended for mammography display and cleared by the regulatory authority in your region or jurisdiction.

Change Healthcare Stratus Imaging PACS is not intended for diagnostic use on mobile devices.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device is an updated version of the predicate device, Change Healthcare Stratus Imaging PACS, also known as Nucleus.io (K203249). The Indications for use for the subject device and the predicate device are equivalent. There is no fundamental change to the device as an image processing and management solution. The indications for use were updated to exclude functions such as "storage, distribution, sharing, networking" of medical images as they no longer fall within the FDA's definition of a medical device. Such changes do not affect the intended use of the software nor create a new intended use.
Neither the subject nor the predicate device is indicated for any specific disease, condition, or patient population, and both devices are not intended for diagnostic use on mobile devices. Therefore, the indications for use of subject and predicate device are considered fundamentally the same, and only includes minor updates such as the removal of non-device functions and rewording for clarification purposes.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device Change Healthcare Stratus Imaging PACS employs the same fundamental scientific technology as its predicate device Change Healthcare Stratus Imaging PACS/Nucleus.io [K203249]. Both devices are cloud based MIMPS and offer diagnostic viewing capabilities relying on DICOM and other industry standards for modes of operations. The feature set is fundamentally the same. Some minor functionality differences between Change Healthcare Stratus Imaging PACS and the predicate devices are that the subject device:
• Integrates with PowerScribe (a 3rd party reporting tool), which enable users to create reports within the integrated tool for studies they are reviewing on the Diagnostic Viewer
• Supports technologists' workflow in Diagnostic Viewer, such as linking, moving, deleting studies etc.
• Enable user to create key images and saving the current presentation state (GSPS) so that the attributes can be later applied to the image
These minor functionality differences do not raise new questions of safety or effectiveness compared to the predicate device. Thus, the subject device is considered substantially equivalent to the predicate device with respect to technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical tests, such as mechanical engineering performance testing, are not applicable to the subject device, as Change Healthcare Stratus Imaging PACS is software-only device (SaMD). During the product development of Change Healthcare Stratus Imaging PACS, software verification and validation tests were conducted in accordance with the Company's Quality Management System, which incorporates design control testing principals defined in the following FDA Guidance documents and FDA recognized consensus standards:
- FDA Guidance for the Premarket Submissions for Device Software Functions, June 14, 2023
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, FDA, CDRH, January 11, 2002
- ISO 14971:2019 Third Edition 2019-12; Medical Devices - Application Of Risk Management To Medical Devices
- IEC 62366-1 Edition 1.1 2020-06 Consolidated Version; Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304 Edition 1.1 2015-06 Consolidated Version; Medical Device Software - Software Life Cycle Processes
Software verification and validation were completed to ensure that the features conformed to all new and previously defined

specifications and any risks were properly mitigated, and that the modifications did not degrade the existing functionality.
All the software specifications have met the acceptance criteria and the software achieved all product release criteria. The testing results did not raise new or different questions of safety and effectiveness other than those already associated with the predicate device.

The comparison of technological characteristics and software validation data demonstrates that the subject device is substantially equivalent in the areas of technical characteristics, functionality, features, and indications for use. The new device does not introduce a fundamentally new scientific technology, and the device has been validated through system level test. Where there are differences between the subject and the predicate devices, those differences are minor and do not raise different questions of safety and effectiveness for the subject device. Therefore, subject device is as safe, as effective, and performs as well as or better than the predicate, Change Healthcare Stratus Imaging PACS/Nucleus.io [K203249].