Change Healthcare Canada Company
% Ms. Nadia Marchant
Executive Director, Quality Assurance & Regulatory Affairs
10711 Cambie Road
Richmond, B.C. V6X 3G5
CANADA

August 29th, 2018

Re: K181185
Trade/Device Name: Change Healthcare Enterprise Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 10, 2018
Received: August 16, 2018

Dear Ms. Marchant:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181185

Device Name
Change Healthcare Enterprise Viewer

Indications for Use *(Describe)*
Change Healthcare Enterprise Viewer is a software-based enterprise viewer intended to be used with off-the-shelf hardware for the 2D and 3D display of DICOM and non-DICOM medical images, reports, and multimedia content. Change Healthcare Enterprise Viewer is intended as well to facilitate collaboration and sharing of these materials within and outside the healthcare enterprise.

Change Healthcare Enterprise Viewer is intended to enable trained healthcare professionals to perform a diagnostic review on a workstation and non-diagnostic review on a mobile device, of a patient's medical images and to aid their clinical decision-making process.

Users access the application on a desktop computer or specific mobile devices through a standard web browser.

Change Healthcare Enterprise Viewer is not intended for diagnostic use on a mobile device. When used on a mobile device, Change Healthcare Enterprise Viewer is not intended to replace full workstations and should only be used when there is no access to a workstation.

Change Healthcare Enterprise Viewer is not intended for primary mammography diagnosis.

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."

510(k) SUMMARY
Change Healthcare Canada Company's Change Healthcare Enterprise Viewer device

Change Healthcare Canada Company
10711 Cambie Road
Richmond, B.C.
Canada, V6X 3G5

510(K) Owner and Contact:	Nadia Marchant Executive Director, Quality Assurance & Regulatory Affairs Change Healthcare Canada Company 10711 Cambie Road Richmond, B.C. Canada, V6X 3G5 Phone: 604.279.5422 Fax: 604.279.5468 E-mail: Nadia.Marchant@McKesson.com
Date Prepared:	August 3, 2018
Proprietary Name:	Change Healthcare Enterprise Viewer
Common/ Usual Name	Enterprise Viewer
Classification Name:	Picture Archiving and Communications System
Classification Regulation:	21 CFR 892.2050
Classification Product Code:	LLZ
Device Class:	Class II
Classification Panel:	Radiology Devices
510(k) Number:	K181185
Predicate Device:	ResolutionMD (K161130), Calgary Scientific

Intended Use/ Indications for Use

Change Healthcare Enterprise Viewer is a software-based enterprise viewer intended to be used with off-the-shelf hardware for the 2D and 3D display of DICOM and non-DICOM medical images, reports, and multimedia content. Change Healthcare Enterprise Viewer is intended as well to facilitate collaboration and sharing of these materials within and outside the healthcare enterprise.

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Change Healthcare Enterprise Viewer is not intended for primary mammography diagnosis.

Device Description

Change Healthcare Enterprise Viewer is an enterprise medical image viewer software application used with off-the-shelf servers, web browsers, and specific mobile devices for the 2D & 3D display of DICOM and non-DICOM medical images, reports, and multimedia content.

Change Healthcare Enterprise Viewer is intended to connect to an existing Picture Archiving and Communication System (PACS) or Vendor Neutral Archive (VNA) and is used to display medical images of multiple for clinical review, sharing and collaboration purposes.

Technological Characteristics

Change Healthcare Enterprise Viewer enables users to view medical images via a web browser. Images are acquired to Change Healthcare Enterprise Viewer from a connected PACS or vendor neutral archive (VNA) and loaded temporarily into memory on a centralized server. The users interact with the server-based application via a browser to view the images.

Users are able to launch the application from an EMR/EHR system with access to a specific patient context encoded into an URL. Users are also able to launch the application by login into the application for authentication purposes and then search any patient of interest to launch the corresponding patient context.

Change Healthcare Enterprise Viewer consists of configurable software-only modules that display and process digital medical images, digital medical video and associated medical information to aid in the day-to-day operations and workflow of clinicians and healthcare practitioners. The software modules include a web browser based medical image viewer and a suite of supporting backend services that access medical images and documents from a variety of sources within the healthcare enterprise. The data from these sources is processed by Change Healthcare Enterprise Viewer in view of preparing visualizations to be rendered by the viewer.

Change Healthcare Enterprise Viewer utilizes authorization and authentication mechanisms, and requires authorized users to access the imaging data. Change Healthcare Enterprise Viewer tracks user activity via audit trails and store the data on the centralized server device. Change Healthcare Enterprise Viewer does not store patient health information, which persists only while the web browser tab displaying the information is active.

Change Healthcare Enterprise Viewer provides end-users with the ability for specialized features such as Window/ Level, Image Flip and Rotate, Invert Intensities, Image Measurements, Annotations, Orientation Label, or Keyboard shortcuts. Measurements and annotations saved from another viewing system as Greyscale Softcopy Presentation State (GSPS) are displayed by default.

Images in Change Healthcare Enterprise Viewer are initially displayed in the 2D view mode, but the view mode can be toggled to 3D/MPR at any time in the image viewer. Change Healthcare Enterprise Viewer supports processing and displaying Multiplanar Reconstruction (MPR) and Maximum Intensity Projection (MIP). In this view mode Change Healthcare Enterprise Viewer provides capability to view a series for different thickness. Change Healthcare Enterprise Viewer provides methods of navigating the data similarly in 2D and 3D views.

Change Healthcare Enterprise Viewer uses built-in image quality adjustment mechanism which provides users with the best resolution that can be handled by the displayed device. Change Healthcare Enterprise Viewer also supports Cine mode which automatically scrolls through images at the current window/level and zoom settings.

Software Verification and Validation testing overview

Verification and Validation testing was performed on Change Healthcare Enterprise Viewer to ensure it met all specifications. The device was further validated to ensure that it performs as intended. Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485:2003, IEC 62304:2006 and ISO 14971:2007. In all instances, Change Healthcare Enterprise Viewer functioned as intended and the observed results demonstrate substantial equivalence with the predicate device.
No clinical studies were necessary to support substantial equivalence.

Substantial Equivalence

Change Healthcare Enterprise Viewer is substantially equivalent to the identified predicate device ResolutionMD (K161130). Specifically, Change Healthcare Enterprise Viewer has the same general intended use and similar indications for use, technological characteristics and principles of operation comparing to the previously cleared predicate device.

The minor technological differences between Change Healthcare Enterprise Viewer and ResolutionMD, its predicate device, raise no new issues of safety or effectiveness. Thus, Change Healthcare Enterprise Viewer is substantially equivalent to the previously cleared predicate device.