Change Healthcare Israel Ltd.
℅ Chester Mccoy
VP, Quality Assurance & Regulatory Affairs and Chief Quality Officer
Change Healthcare Canada Company
10711 Cambie Road
Richmond, British Columbia V6X3G5
CANADA

October 18. 2021

Re: K212528
Trade/Device Name: Change Healthcare Cardiology™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 5, 2021
Received: August 11, 2021

Dear Chester Mccoy:

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,

For

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: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212528

Device Name

Change Healthcare Cardiology™

Indications for Use *(Describe)*

Change Healthcare Cardiology™ is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital cardiovascular images and information from other data sources.

Change Healthcare Cardiology™ is intended for use in the Cardiology, Radiology or other departments throughout the healthcare facility and distributed locations and may be part of a larger PACS configuration.

Change Healthcare Cardiology™ offers support for third party plug-ins in order to enable the use of commercially available tools for analysis, quantification and reporting.

Change Healthcare Cardiology™ is intended to assist trained professionals in the viewing and diagnostic interpretation of images and other information for the diagnosis and treatment of cardiac and vascular disease.

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.

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510(k) SUMMARY

K212528

Change Healthcare Canada Company

Change Healthcare Canada Company
10711 Cambie Road
Richmond, British Columbia, V6X 3G5
Canada

Contact Person:	Chester McCoy, Vice President, Quality Assurance and Regulatory Affairs, and Chief Quality Officer Change Healthcare Canada Company 10711 Cambie Road Richmond, British Columbia, V6X 3G5, Canada Telephone: (574) 302-5855 Email: Chester.McCoy@changehealthcare.com
Date Prepared:	September 27, 2021
Name of the device:	Change Healthcare Cardiology™
Common or Usual Name:	System, Image processing, Radiological
Classification Name:	Medical image management and processing system.
Classification Regulation:	21 C.F.R. § 892.2050
Product code:	LLZ
Device Class:	Class II
Predicate Device:	McKesson Cardiology™ (K181080)

Intended Use and Indications for Use

Change Healthcare Cardiology™ is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital cardiovascular images and information from other data sources.

Change Healthcare Cardiology™ is intended for use in the Cardiology, Radiology or other departments throughout the healthcare facility and distributed locations and may be part of a larger PACS configuration.

Change Healthcare Cardiology™ offers support for third party plug-ins to enable the use of commercially available tools for analysis, quantification, and reporting. Change Healthcare Cardiology™ is intended to assist trained professionals in the viewing and diagnostic interpretation of images and other information for the diagnosis and treatment of cardiac and vascular disease.

Technological Characteristics

Change Healthcare Cardiology™ is a software application intended to run on a client/server array in a physical or virtual hosting environment to allow:

- Importation of images in DICOM format, final reports, and various discrete data elements
- Review, editing, management and synchronization of patient information and procedure data
- Storage and management of data elements (images, reports, discrete data, and so on) for long term archive and disaster recovery purposes
- Review, performance and editing of measurements
- Creation, editing and confirmation of procedure reports
- Distribution of procedure reports and results to other systems in file or discrete data element formats
- Integration with 3rd party software components to provide additional image review, measurement tools, reporting and/or data import/export capabilities
- Departmental administrative tasks such as managing charges and billing, departmental stock inventory levels, and so on.

New additional features and functionalities in this version and subject of this submission include:

- Reporting module was redesigned on web based technology improving former reporting version capabilities:
    - New Change Healthcare Cardiology Vascular Ultrasound Report:
        - Step-by-step design to accommodate the user's workflow
        - Enhanced Vascular Diagrams
        - Enhanced efficiency of filling in clinical findings
        - Predefined content ease data insertion
    - New Change Healthcare Cardiology Adult Echo Report:
        - Step-by-step design to accommodate the user's workflow
        - Improved data display
        - Enhanced efficiency of filling in clinical findings
- Change Healthcare Cardiology Reference Viewer was renewed and is now fully zero footprint

- Change Healthcare Cardiology Web was aligned with Change Healthcare Cardiology™ client capabilities:
    - Added functionalities to the procedure list
    - Improved viewer display and functionalities
    - Enhanced measurements in the viewer
    - Added DICOM protocol transfer capabilities
    - Launch of additional viewing third parties
- Report Editor has been enhanced to allow administrators to perform a broader range of customizations. They can customize:
    - The new Change Healthcare Cardiology Vascular Ultrasound Report
    - The new Change Healthcare Cardiology Adult Echo Report
- Adaptive Archiving and IOCM (Imaging Object Change Management) were built for VNA (Vendor Neutral Archive) interoperability as the DICOM Archive
- Added security, privacy and cybersecurity enhancements

Performance Data

Verification and validation testing was performed on Change Healthcare Cardiology™ to ensure it met all specifications. In addition, usability testing was performed where applicable. The device was further validated to ensure that it performs as intended. Performance testing was conducted to verify compliance with specified design requirements under IEC 62304:2015, IEC 62366-1:2015, and ISO 14971:2007, which are FDA Guidelines for Cybersecurity and Interoperability.

Furthermore, DICOM conformance testing was performed to verify compliance with NEMA 3.1-3.20 (2016) standards. No clinical studies were necessary to support substantial equivalence. In all instances, Change Healthcare Cardiology™ functioned as intended and the observed results demonstrate substantial equivalence with the predicate devices.

Substantial Equivalence

Change Healthcare Cardiology™, the subject of this submission, is substantially equivalent to the previously cleared McKesson Cardiology™ (K181080). Change Healthcare Cardiology™ has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate device.

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