Change Healthcare Israel Ltd.
℅ Mr. Paul Sumner
Sr. Director, Compliance & Regulatory Affairs
Change Healthcare Technologies LLC
5995 Windward Parkway
ALPHARETTA GA 30005

May 24, 2018

Re: K181080
Trade/Device Name: McKesson Cardiology™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 12, 2018
Received: April 24, 2018

Dear Mr. Sumner:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K181080

Device Name
McKesson Cardiology™

Indications for Use *(Describe)*

McKesson 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.

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

McKesson 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
Change Healthcare Israel Ltd.'s McKesson Cardiology

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Date Prepared: April 08, 2018

Name of the device:	McKesson Cardiology™
Common or Usual Name:	Imaging Processing System
Classification Name:	Picture archiving and communications system
Classification Regulation	21 C.F.R. § 892.2050
Product code:	LLZ
Device Class:	Class II
Predicate Device:	Change Healthcare Israel Ltd.'s McKesson Cardiology™ (K151850)

Intended Use / Indications for Use

McKesson 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.

McKesson 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.

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

McKesson 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.

The version of McKesson Cardiology which is the subject of this 510K notification, includes new additional features and enhanced functionality compared to the cleared version. These changes were introduced in the product in order to improve overall user experience and workflow. The changes introduced do not adversely affect or raise any new issues of safety or effectiveness in the product.

Technological Characteristics

McKesson Cardiology™ is an image processing system. The device consists of the following components and accessories: software application; database server; web server; application server; image and document storage server and media; long-term archive and disaster recovery media; and client application workstation.

New additional features and functionalities in this version and subject of this submission include:
- MC-D (distributed web client application) patient list was redesigned as a browser based procedure list application
- Procedure priority indication – new display of procedure priority level
- MRN aggregation – option to review aggregated list of all patient procedures in MC-D for patients with multiple procedures from different facilities
- VNA Interoperability – Imaging Object Change Management (IOCM)
- Vascular report redesigned as a browser based module
- Multi-facility Support
- New platform qualifications
- EMR integration enhancements
-Added security, privacy and cybersecurity enhancements

Performance Data

Verification and validation testing was performed on McKesson 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 in accordance with ISO 13485:2003, IEC 62304:2015 and ISO 14971:2007, 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, McKesson Cardiology functioned as intended and the observed results demonstrate substantial equivalence with the predicate devices.

Substantial Equivalence

McKesson Cardiology™, the subject of this submission, is substantially equivalent to Change Healthcare Israel's Ltd.'s previously cleared McKesson Cardiology™ (K151850). McKesson Cardiology™ has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate device.

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