DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 11, 2015

McKesson Israel Ltd.
% Mr. Paul Sumner
Director, Regulatory Affairs
McKesson Technologies, Inc.
5995 Windward Parkway
ALPHARETTA GA 30005

Re: K151850
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: July 7, 2015
Received: July 8, 2015

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151850

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.

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Food and Drug Administration
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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

McKesson Israel Ltd.
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Date Prepared: August 5, 2015

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:	McKesson Israel Ltd.'s Horizon Cardiology™ (K112720)
Reference Device:	GE Medical Systems' Centricity Cardio Imaging (K112570)

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, subject of this 510(k), allows for the provision of additional information from expanded data sources to assist trained healthcare professionals

throughout the healthcare facility and distributed locations in diagnosing and treating cardiac and vascular diseases.

The expansion of the indications for use to include other data sources and the usage of the device in distributed locations does not raise new questions of, or adversely affect the safety or effectiveness of the device. The intended use of McKesson Cardiology™ as a result of these changes remains the same as the predicate(s) and do not raise new questions as a result, or affect safety and effectiveness.

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.

The version of McKesson Cardiology, subject of this 510(k) includes enhancements and new features including those for supporting dictation and streamlining user workflow for documenting, charting and trending procedural related data for Cath and other reporting; Statistical data collection of non-invasive features use for adoption considerations; Security; DICOM display view; Storage and archival enhancements; Support for stress modalities XML data import; EP modalities data import and reporting; and, importing lab results and exporting procedure medications using standard HL7.

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 62304:2006 and ISO 14971:2007. Furthermore, DICOM conformance testing was performed to verify compliance with NEMA 3.1-3.20 (2011) 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™ is substantially equivalent to McKesson Israel's Ltd.'s Horizon Cardiology™ (K112720), as well as GE Medical Systems' Centricity® Cardio Imaging (K112570). McKesson Cardiology™ has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices.

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