

JUL 02 2014

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510(k) SUMMARY
McKesson Medical Imaging Company's McKesson Radiology Device

McKesson Medical Imaging Company
130 – 10711 Cambie Road
Richmond, B.C.
Canada, V6X 3G5

510(k) Owner and Contact: Gilbert Wong
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Canada V6X 3G5

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Date Prepared: March 31, 2014

Proprietary Name: McKesson Radiology™
Common/Usual Name: PACS
Classification Name: Picture Archiving Communications System
Classification Regulation: 21 CFR 892.2050
Classification Product Code: LLZ
Device Class: Class II
Classification Panel: Radiology Devices
Predicate Devices: Horizon Medical Imaging (K043146)
Fuji Synapse Workstation Software (K051553)

Intended Use / Indications for Use

McKesson Radiology™ is medical image and information management software that is intended to receive, transmit, store, archive, retrieve, manage, display, print and process digital medical images, digital medical video and associated patient and medical information. McKesson Radiology includes a suite of standalone, web-enabled software components, and is intended for installation and use with off-the-shelf hardware that meets or exceeds minimum specifications.

McKesson Radiology Station™ is the primary software component used for processing and presentation of medical images on display devices with network access to McKesson Radiology. McKesson Radiology Station is intended to process and display lossless and

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non-lossless compressed medical images provided from DICOM conformant modalities such as X-Ray Radiography (including digital mammography), X-Ray Computed Tomography, Magnetic Resonance Imaging, Ultrasound, and Nuclear Medicine, as well as medical images obtained from other DICOM-compliant modalities.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

Mammographic images may only be interpreted using cleared monitors intended for mammography display.

McKesson Radiology is indicated for use by qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists.

Technological Characteristics

McKesson Radiology, a Picture Archiving and Communication System (PACS), consists of configurable software-only applications that receive, transmit, store, archive, retrieve, manage, display, print and process digital medical images, digital medical video and associated patient and medical information to aid in the day-to-day operations and workflow of clinicians and healthcare practitioners. It includes the primary diagnostic viewer McKesson Radiology Station, clinical-reference viewers, workflow tools and administrative tools. Although the primary McKesson Radiology functionalities, such as DICOM study acquisition, storage, and archival, are intended to be installed and used within a hospital or health care facility environment, the viewing, reporting and administrative functions are intended for use both inside and outside of these settings by qualified healthcare practitioners.

Performance Data

Verification and validation testing was performed on McKesson Radiology 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/EN 14971:2012. In all instances, McKesson Radiology functioned as intended and the observed results demonstrate substantial equivalence with the predicate devices.

Substantial Equivalence

McKesson Radiology is substantially equivalent to the identified predicate devices which include the cleared Horizon Medical Imaging device (K043146) and the Fuji Synapse Workstation Software (K051553), as well as other similar, if not identical, legally commercially available devices in U.S. Interstate commerce. Specifically, McKesson Radiology has the same general intended use and similar indications for use,

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technological characteristics and principles of operation compared to these previously cleared predicate devices.

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



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

McKesson Medical Imaging Company
% Mr. Paul Sumner
Director, Regulatory Affairs
McKesson Technologies, Inc.
5995 Windward Parkway
ALPHARETTA GA 30005

July 2, 2014

Re: K140909
Trade/Device Name: McKesson Radiology
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 24, 2014
Received: June 27, 2014

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.

Page 2—Mr. Sumner

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

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140909

Device Name
McKesson Radiology™

Indications for Use (Describe)

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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."