K133534

510(k) SUMMARY
McKesson Israel Ltd.'s McKesson Cardiology™ ECG Mobile

APR 18 2014

McKesson Israel Ltd.
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Date Prepared: April 2, 2014

Name of the device: McKesson Cardiology™ ECG Mobile
Common Name: McKesson Cardiology™ ECG Mobile

Classification Name: Programmable diagnostic computer
Classification Regulation: 21 CFR § 870.1425
Product code: DQK
Device Class: Class II

Predicate Device: McKesson Israel Ltd., Horizon Cardiology ECG Management (K113515), AirStrip Technologies, LP, AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing (K122133)

Intended Use / Indications for Use

McKesson Cardiology ECG Mobile is a software application used for accessing and displaying ECG data and related patient information previously stored, analyzed or retrieved by the Horizon Cardiology ECG Management device. The McKesson Cardiology ECG Mobile software application is intended to be used from a mobile device to perform the following:

- View ECG test results, such as waveforms, synopsis measurements and diagnosis statements, as well as other relevant current or historical patient information originally stored, analyzed or retrieved by the Horizon Cardiology ECG Management device.
- View the ECG lead traces using different display settings.
- Compare the results of current ECG tests with any previous ECG test results stored on the Horizon Cardiology ECG Management device.
- Perform ECG-related measurements and edit synopsis measurement values stored on the Horizon Cardiology ECG Management device.
- Enter new diagnosis statements and/or modify diagnosis records stored on the Horizon Cardiology ECG Management device.
- Confirm ECG procedures and results.
- Communicate information with the Horizon Cardiology ECG Management device such as login credentials and user settings.

McKesson Cardiology™ ECG Mobile application is intended to be used under the direct supervision of a licensed healthcare practitioner and by trained operators. McKesson Cardiology™ ECG Mobile is not intended for real time monitoring.

Technological Characteristics

McKesson Cardiology ECG Mobile provides secure access to ECG records and related information contained on the Horizon Cardiology ECG Management device. The McKesson Cardiology ECG Mobile software functions as an accessory to the Horizon Cardiology ECG Management device, and requires a WiFi or cellular connection to a pre-installed and properly configured Horizon Cardiology ECG Management device. Through providing remote access to the ECG data stored on the McKesson Cardiology ECG Management device, the user is able to review current and previous ECG tests results, perform measurements on the ECG waveforms, and edit and confirm the ECG test results. McKesson Cardiology ECG Mobile does not store ECG or patient related information on the mobile device, does not directly communicate with cardiographs or other waveform acquisition devices, and does not use any automatic electronic data processing and pattern recognition methods to derive measurements (e.g. intervals and amplitudes) or provide diagnostic statements from the ECG data. The device does not allow modification of the original ECG traces (waveforms) stored on the Horizon Cardiology ECG Management device.

The McKesson Cardiology ECG Mobile application is not intended to replace the functionalities provided by the Horizon Cardiology ECG Management desktop client but to extend those to make selected functionalities described above available via mobile devices.

The McKesson Cardiology ECG Mobile functions as a non-real time system and is not intended for real time monitoring.

McKesson Cardiology ECG Mobile can be used both inside and outside of medical facilities except in areas where cellular phone or wireless device use is prohibited.

McKesson Cardiology ECG Mobile is intended to operate on Apple®iPad running iOS mobile operating system from Apple Inc.

Performance Data

Non-clinical testing performed included software verification, validation, and security testing to ensure that the McKesson Cardiology™ ECG Mobile met all design specifications and requirements. Unit and system level testing included assurance of operability with the predicate Horizon Cardiology ECG Management device and user accuracy qualification of ECG waveform and related information representation in a simulated user test environment.

Performance testing additionally included clinical qualification and usability testing (human factors testing) involving intended McKesson Cardiology ECG Mobile clinical users in the clinical setting for reviewing, comparing, and rating the use and display quality of the ECG Mobile device.

Clinical Qualification testing performed verified the McKesson Cardiology ECG Mobile display and measurements acquisition capabilities using sample cases selected by a clinician based on technical characteristics and relevancy to the intended function of the McKesson Cardiology ECG Mobile application. The testing considered parameters such as gender, age groups and clinical characteristics,

different display manipulations (e.g. zoom, comparing the morphology, editing the synopsis value, navigating between screens), display quality and accuracy when compared to the original data as presented by Horizon Cardiology ECG Management.

Usability testing was conducted by three (3) U.S. medical facilities and in environment simulating a real use of the application for validating that human factors in using the device were sufficiently addressed. In particular, the testing was performed to ensure adequate user readability and image quality on a small screen and that users with varying qualifications could use the device.

In all instances, the McKesson Cardiology™ ECG Mobile functioned as intended by the design requirements, and the observed results demonstrated substantial equivalence with the predicate devices.

Substantial Equivalence

McKesson Cardiology™ ECG Mobile has the same intended use, similar indications, technological characteristics and principles of operation as the predicate devices. All of the devices display ECG patient and procedure data, and allow for editing, interpretation, and confirmation by an over-reading physician.

Any differences between the predicate devices and McKesson Cardiology™ ECG Mobile do not raise any new types of safety or efficacy questions. In summary McKesson Israel, Ltd. is of the opinion that the McKesson Cardiology™ ECG Mobile is substantially equivalent to the company's Horizon Cardiology™ ECG Management (K113515), as well as AirStrip Technologies, LP, Airstrip Remote Patient Monitoring (RPM) Remote Data Viewing (K122133).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 2, 2014

McKesson Israel Ltd.
Paul Sumner
5995 Windward Parkway
Alpharetta, GA 30005 US

Re: K133534
Trade/Device Name: McKesson Cardiology ECG Mobile
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: March 20, 2014
Received: March 25, 2014

Dear Paul Sumner,

This letter corrects our substantially equivalent letter of April 18, 2014.
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" (21CFR 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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known):_____

Device Name: McKesson Cardiology™ ECG Mobile

Indications for Use:

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- Communicate information with the Horizon Cardiology ECG Management device such as login credentials and user settings.

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The McKesson Cardiology ECG Mobile application is not intended for real-time monitoring.

Prescription Use (Part 21 CFR 801 Subpart D)	___X___	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.06.06
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