K120320

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510(k) Summary for Watermark Medical Connected Care Clinical Application

AUG 14 2012

Submitter:	Watermark Medical
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Telephone:	877-710-6999
Establishment Registration #:	3008208119
Submission Contact:	Michael J. Leigh, consultant 12715 Falcon Drive Brookfield, Wisconsin 53005 Ph: (262) 957-6797
Trade Name:	Connected Care Clinical Application
Predicate Device:	Honeywell HomMed Central Station, K072272
Common Name:	Patient Vital Signs Monitor Viewing Station

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
870.1130	DXN	System, Measurement, Blood-Pressure, Non-Invasive	II
Medical Device product codes also supported by Clinical Application by means of separate medical devices			
880.2700	FRI	Patient Weight Scale	I
870.270	DQA	Oximeter	II
862.1345	NBW	Glucose Test System	II

Device Description:

The Connected Care Clinical Application is a cloud based, web software system. It is accessed from commercially available PC systems with a web browser and minimum performance specifications consistent with typical PC hardware and equipment specifications. The Clinical Application accepts data from Watermark Patient Monitors.

The Connected Care Clinical Application is a medical device data system that receives, stores, and displays data received from Watermark home monitoring devices. Additionally, it can send configuration information to Watermark home monitoring devices. Watermark devices include the Mobile Application and MiPal. The configuration information may include a patient's vitals collection schedule and parameters to be collected.

Intended Use:

Clinical Application's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. The Web Application displays the data and system alerts for review and interpretation by a healthcare professional. The Web Application is not intended for emergency use or real-time monitoring.

Performance Data:

The software validation results demonstrated that the Clinical Application was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding medical device software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 14 2012

Watermark Medical, Inc.
c/o Mr. Michael J. Leigh
Consultant
12715 Falcon Drive
Brookfield, WI 53005

Re: K120320
Trade/Device Names: Watermark Connected Care Clinical Application
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN, FRI, DQA, NBW
Dated: April 27, 2012
Received: July 18, 2012

Dear Mr. Leigh:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120320

Device Name: Watermark Medical Connected Care Clinical Application

Indications For Use:

Clinical Application's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. Additionally, it can send configuration information to Watermark home monitoring devices. Watermark devices include the Connected Care Mobile Application and MiPal. The configuration information may include a patient's vitals collection schedule and parameters to be collected. The Clinical Application displays the data and system alerts for review and interpretation by a healthcare professional. The Clinical Application is not intended for emergency use or real-time monitoring.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120320