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OCT - 6 2011

510(k) Summary

GENERAL COMPANY INFORMATION
COMPANY NAME/ADDRESS/PHONE/FAX:

Ascot Technologies, Inc.
267 Hogans Valley Way
Cary, NC 27513
Tel: 919-388-1776
Fax: 919-481-3203

NAME OF CONTACT:

Mary Ellen Randall
President
(919) 388-1776

DATE PREPARED: Original December 8, 2010
Updated February 2, 2011
Updated September 18, 2011
Updated October 5, 2011

TRADE NAME:
Ascot Home Medical Monitoring System (HMMS)

COMMON NAME:
Health Management System Software

DEVICE NAME:
Ascot Home Medical Monitoring System (HMMS)

CLASSIFICATION NAME:

The following classifications appear applicable:

Product Code	Classification Name	Class	CFR Section
DRG	Radiofrequency physiological signal transmitter and receiver	II	870.2910

COMPARISON TO PREDICATE DEVICE

We claim substantial equivalence to the currently legally cleared ACCU-CHEK® Advisor Insulin Guidance Software (K043529) and OneTouch® Zoom™ Diabetes Management Program (K081318), Confidant 2.6 (K083331), and FORA GW 9014 TeleHealth Gateway Telemedicine System (K100427).

COMPARISON TO PREDICATE DEVICE

Feature/ Claim	ACCU-Chek® Advisor Software	OneTouch® Zoom™ Diabetes Management Program	Confidant 2.6	FORA Telehealth Gateway	Ascot HMMS
Data Upload	Yes	No. Data obtained from DataVault	Yes through standard communicati on technologies.	Yes through standard communicati on technologies.	Yes through standard RS232, Bluetooth or USB Connection
Support	Through call center support, labeling & health care professionals	Unknown.	Unknown	Unknown	Through trained health care staff, staff training, written instructions & Ascot support.
Data Storage	On computer media	On computer media	On computer media	On Computer media	On computer media
Reports & Graphs	Based on readings obtained	Based on readings obtained	Based on readings obtained	Based on readings obtained	Based on readings obtained
Review Readings	On Computer	Web Interface	On cell phone.	Web Interface	Web Interface
Enables patient & health care professional to share readings	Yes	Yes.	Yes.	Yes.	Yes.
Provides feedback to patient	No.	No.	Yes. Automated.	No.	Yes. Authorized By Physician only.
Devices Supported	Blood Glucose	Blood Glucose	Blood glucose, non-invasive blood pressure, weight.	Blood glucose, blood pressure, Weight, temp, body fat, hydration.	Blood glucose, non-invasive blood pressure.

Feature/ Claim	ACCU-Chek® Advisor Software	OneTouch® Zoom™ Diabetes Management Program	Confidant 2.6	FORA Telehealth Gateway	Ascot HMMS
Intended Use: Home setting	Yes.	Yes.	Yes.	Yes.	Yes.
Method of transmitting data to physician	Brought in at appointment, read off patient's machine or called in to Physician.	Transmitted across computer connection to remote database hosted by Microsoft.	Unknown. Readings are transmitted to a central database.	Transmitted across standard computer connection to remote database.	Transmitted across secure computer connection to Ascot server database.
WebViewer	No. Patient brings in readings.	Readings read through HealthVault account.	Feedback to patient's cell phone.	Yes.	Yes. Readings transmitted eliminating reporting errors.
Provides Diagnosis	No.	No.	No.	No.	No.

DEVICE DESCRIPTION

The HMMS is automation of the existing process of reporting readings to the physician over the phone and receiving verbal instructions for dosage changes. New prescriptions are not handled or ordered in the HMMS.

The Ascot HMMS (Home Medical Monitoring System) is a software based device which receives readings in the home or clinical setting from various FDA approved devices (such as home Blood Pressure monitor with pulse or Glucose testing monitor) and transmits readings to the Ascot Central Server (ACS) for review by the Physician. (For the purposes of this submission, Physician refers to a qualified medical professional who can change medication dosages, such as Nurse Practitioners or Physician Assistants.) If the Physician modifies medication dosages, the patient medication dosage instructions ordered by the Physician, are transmitted back to the patient and displayed on the HMS. Receipt of each transmission is confirmed within the system.

The Ascot HMMS (Home Medical Monitoring System) reduces risks to health because it speeds up the communication between the Physician and the patient. It improves accuracy because readings are transmitted directly from the home to server for later review by the Physician.

If the patient prefers, they may still report readings using the former process.

Devices which have been tested to operate with the Ascot Home Medical Monitoring System include:

Device Name	File Number	How Connected	Type Device
OneTouch Ultra Mini	K061118	Serial Cable	Blood Glucose Monitor
OneTouch Ultra 2	K053529	Serial Cable	Blood Glucose Monitor
OneTouch UltraLink	K073231	Serial Cable	Blood Glucose Monitor
Omron HEM-790IT (Product Line extension of Model HEM780N3)	K061822	USB Cable	Automatic Blood Pressure Monitor (includes pulse)
HoMedics BPA-260-CB (Model HL868BF)	K092161	USB Cable	Blood Pressure Monitor (includes pulse)

INTENDED USE

The HMMS is automation of the existing process of reporting readings to the physician over the phone and receiving verbal instructions for dosage changes. New prescriptions are not handled or ordered in the HMMS.

The HMMS is intended for use in the home or at clinical settings as a means to collect physiological readings, measured by FDA approved devices, and transmit to a Physician for review. The readings are accessed by a qualified medical professional (such as Physician or Nurse Practitioner) for review. The qualified medical professional may make medication dosage changes and transmit those changes back to the patient. The patient confirms the receipt of the medication changes. The changes are displayed on the patient's Ascot Home Medical Station (HMS).

The HMS receives readings measured by various FDA approved medical devices (such as blood pressure with pulse or blood glucose monitor) via standard connections including RS232, Bluetooth, or USB connection. The HMS communicates with the Ascot Central Server (ACS) via standard wireless or wired communication protocols including cellular data and wireless internet.

The HMMS does not make any decisions on the data that it conveys.

The HMMS does not provide diagnosis of any disease or medical condition.

The HMMS is not a substitute for professional healthcare judgment.

The HMMS uses standard communication protocols and encryption to protect patient privacy.

The HMMS Viewer is not a primary alarm source.

The full viewer is for use by qualified medical personnel only.

There is a limited viewer interface for use by the patient in reviewing their own readings and staff for adding notes to patient file and follow up call, if instructed by Physician.

End of 510(k) Summary Section

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

Ascot Technologies, Inc.
c/o Ms. Mary Ellen Randall
President
267 Hogans Valley Way
Cary, NC 27513

OCT - 6 2011

Re: K103643
Trade/Device Name: Ascot Home Medical Management System (HMMS)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: September 18, 2011
Received: September 20, 2011

Dear Ms. Randall:

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 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
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K103643

Device Name: Ascot Home Medical Monitoring System (HMMS)

Prescription Use
This medical device is indicated for use by patients with known or suspected hypertension or diabetes that a physician wants to monitor blood pressure, pulse, and/or blood glucose at home.

This medical device is a software based device which runs on a Windows based Computer or netbook. This medical device receives readings from supported FDA approved devices in the home and serves as a remote communication link between the home and the physician or qualified medical provider. The physician or qualified medical provider will review the patient information from a web interface and may make medication changes and transmit those changes back to the patient for display on the Home Medical Station(HMS).

This medical device receives blood pressure, heart rate and blood glucose readings from the supported FDA approved medical devices via USB or serial connection to the HMS. The HMS communicates with the server via standard wireless or wired communication protocols such as cellular data, and wired or wireless internet.

HMMS has been tested to work with Homedics BPA-260-CBL, Omron HEM-790IT and OneTouch Ultra Mini, OneTouch Ultra 2 and OneTouch UltraLink.

This medical device is automation of the exiting process of reporting results to the physician over the phone.

This medical device is not intended to provide real time monitoring. It is not intended for emergency calls or for transmission of any time-critical data. This device is not intended as a substitute for direct medical supervision or emergency intervention.

This medical device does not provide diagnosis of any disease or medical condition and is not a substitute for professional healthcare judgment.

This medical device uses standard communication protocols and encryption to protect patient privacy.

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

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103643