JUL 0 8 2013

510(k) SUMMARY

510(k) Owner:	Arrayent Health LLC /dba Ambio Health	
	Contact: Kevin Jones, CEO	
Date Summary Prepared:	March 15, 2012	
Device:	Trade Name:	Ambio Remote Health Monitoring System
	Common/Classification Name:	Remote Patient Monitoring System
	Classification:	Class II
Predicate Devices:	K062377 MedApps 2.0 – Remote Patient Monitoring System K111932 Positive ID – iglucose™ Device, Secure Database, Diabetes Management Portal K080798 Intel Health Guide PHS6000	

Intended Use: The Ambio Remote Health Monitoring System ("System") consists of Ambio Wireless Connectors to send readings from off-the-shelf blood pressure and blood glucose meters, the Ambio Scale with built in wireless connectivity to send readings through the Ambio Gateway to the Ambio Care Portal. The Care Portal is used by patients and their authorized caregivers ("Users") to view readings, set reminders, set personalized thresholds which will trigger alert messages. Reading history can be printed or exported. Users can set goals and rewards for taking readings per their schedule and for achieving reading targets. Users can maintain an exercise log, food log and records of doctor visits and lab tests. Users can create patient surveys to gather qualitative information. Users can coordinate using a shared calendar and message board. Health information from accredited sources can also be displayed.

The Ambio Remote Health Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The System does not alter the indicated use of the described blood pressure or blood glucose monitors.

System Description:

The System consists of:

(1) Ambio Wireless Connectors (Wireless Connectors):

The Wireless Connector is an electronic device that plugs into the USB port of compatible Blood Pressure Monitors and Blood Glucose Monitors to read the log, encrypt the data, and wirelessly transmit the data to the Ambio Gateway. Readings are sent automatically based on a schedule stored in the Wireless Connector or, the User can push the button on the Wireless Connector to initiate reading the Monitor log and transferring the data.

(2) Ambio Scale

The Ambio Scale is a stand on digital weight scale with an embedded Ambio Wireless Connector. When the User takes a weight reading, it is then encrypted by the Ambio Wireless Connector and wirelessly transmitted to the Ambio Gateway.

(3) Ambio Gateway

The Ambio Gateway is an electronic device that connects to the Patient's existing home Internet router using an Ethernet cable. The Ambio Gateway wirelessly receives encrypted data from the Ambio Wireless Connector and transmits it through the user's home broadband internet router to the Ambio Care Portal.

(4) Ambio Care Portal

The Ambio Care Portal is a secure, web based data base and software application that allows Users to review patient data collected from the described health devices using the Ambio Wireless Connector and Ambio Gateway.

The Care Portal is used by patients and their authorized caregivers ("Users") to view readings, set reminders, set personalized thresholds which will trigger alert messages. Reading history can be printed or exported. Users can set goals and rewards for taking readings per their schedule and achieving readings target. Users can maintain an exercise log, food log and records of doctor visits and lab tests. Users can create patient surveys to gather qualitative information. Users can coordinate using a shared calendar and message board. Health information from accredited sources can also be displayed.

Technological Characteristics: The operation of the System is the same as the predicate devices in all respects other than the wireless protocol and frequency used to communicate readings from the health meter / Wireless Connector to the Gateway. Predicate devices use Bluetooth (2.402 to 2.48 GHz) or GSM Cellular (850 / 900 / 1800 / 1950 MHz) as the wireless technology and the subject device uses the 900MHz (902 – 928MHz) band approved by the FCC for unlicensed communication equipment.

Attribute	**MedApps Remote Patient Monitoring Device** **K112559**	**IDEAL LIFE Pod** **K080538**	**Positive ID Iglucose System** **K111932**	**Subject Device (Ambio Health Remote Health Monitoring System)**
Indications of Use	Enables healthcare providers to monitor and manage chronic conditions of patients remotely Flag readings based on specific thresholds being exceeded. Maintain compliance to schedules. Graphic trending.	Enables people at home and healthcare providers to review and evaluate historical blood glucose, weight and blood pressure test results	Enables people at home and healthcare providers to review and evaluate blood glucose data as an aid in supporting diabetes management. Graphic trending.	Enables people at home and healthcare providers to monitor and manage chronic conditions of patients remotely Flag readings based on specific thresholds being exceeded. Maintain compliance to schedules. Graphic trending.
Intended use	Telemedicine System	Same	Same	Same
Intended Users	Home users and Healthcare Providers	Same	Same	Same
Site of Use	Home, Clinic	Same	Same	Same

Data Collection Software Functionality	Transmit data from sensor devices to Central Database	Same	Same	Same
Communication method of hub with Central Server	Cellular	Internet or Telephone line	Cellular	Internet
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home Use: Glucose Scale Blood Pressure PulseOx	Medical Devices designed for Home Use: Glucose Scale Blood Pressure	Medical Device design for Home Use: Glucose	Medical Devices designed for Home Use: Glucose Scale Blood Pressure
Sensor Software	Sensor Software unchanged	Same	Same	Same
Implementation Method of collecting data from sensors	Wireless (Bluetooth) and Wired (tethered) cables	Wireless	Data cable	Data cable (one end of Wireless Connector)
Connectivity	Wireless (Bluetooth) and Wired (tethered) cables	Wireless (Bluetooth) and Wired SmartCable	Data cable	Wireless (900 MHz - other end of Wireless Connector)
Communication method of hub with devices	Wireless (Bluetooth) and Wired (tethered) cables	Wireless (Bluetooth) and Wired (tethered) cables	Cellular	Wireless (900MHz)
Communication Protocol	Wireless (Bluetooth) and Wired (tethered) cables	Wireless (Bluetooth) and Wired (tethered) cables	Cellular	Wireless (900MHz)

Communica-tion Frequency	Bluetooth 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 MHz	Bluetooth 2.402 to 2.48 GHz	GSM: 850 / 900 / 1800 / 1950 MHz	900MHz (902-928 MHz)
Power Source	Wall power plug (120 VAC/50-60) Rechargeable Batteries in HealthPAL	Wall power plug (120 VAC/50-60)	Wall power plug (120 VAC/50-60) and rechargeable battery in iGlucose	Wall power plug (120 VAC/50-60) and coin cell battery in Wireless Connector
Visual Feedback / Display	LED Light indicators	Same	Same	Same
Communica-tion with Patients	Audio/visual reading feedback from LED light indicators & audio tones; Interactive Voice Response (IVR) system for patient contact	Data is viewed in a web-based application; sent via email, SMS text and fax.	Data is viewed in a web-based application; sent via email, SMS text and fax.	Data is viewed in a web-based application; sent via email, SMS text and IVR.

Performance Data:

Non-clinical Testing

The submitted system was found to be compliant to the following standards based on testing performed by Intertek Testing Services:

1. IEC 60601-1 Issue1988/12/01 Ed:2 Medical Electrical Equipment Part 1: General Requirements for Safety; (Amd. 1-1991) (CENELEC EN 60601-1: 1990) (Amd. 2-1995) (Corrigendum-1995)
2. IEC 60601-1-1 Issued:2000/12/01 Ed:2 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety
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   P 6/6

3. Requirements for Medical Electrical Systems

4. IEC 60601-1-4 Issue:2000/04/01 Ed:1.1 Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems; Edition 1:1996 Consolidated
5. IEC/EN 60601-1-2 (Ed. 2): 2001 +A1: 2004 - Medical electrical equipment, Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests. with Amendment 1:1999

The submitted system has undergone Ambio Health's design control verification and validation testing. Ambio Health validation testing includes testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation or the User Guide.

Ambio Health System verification and validation activities as part of the design control process include testing of all Design Specifications based on risk analysis and verification plans. Ambio Health System test plan execution ensures each type of user accessory medical device (glucose, blood pressure, scale) works with the Ambio Wireless Connector and Gateway components and the Ambio Care Portal software. The output of these design control verification analysis documents Ambio Remote Health Monitoring System shall meet its requirements and design specifications as intended.

Arrayent Health used its Risk Management Plan to perform risk analysis regarding human factors for usability to determine that there are no significant risks.

Conclusions: The performance data discussed in this 510(k) application demonstrate that the Ambio Health - Remote Patient Monitoring System is as safe and effective, as the predicate devices.

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

July 8, 2013

Arrayent Health LLC d/b/a Ambio Health
c/o Mr. Kevin Jones
CEO
1266 E Main Street
Stamford, CT 06902

Re: K130676
Trade/Device Name: Ambio Remote Health Monitoring System
Regulatory Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: II (two)
Product Code: 74 DRG
Dated: May 13, 2013
Received: May 14, 2013

Dear Mr. Jones:

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,

Owen P. Faris -S

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

Enclosure

K130676

Indications for Use

510(k) Number (if known): Not assigned.

Device Name: Ambio Remote Health Monitoring System

The Ambio Remote Health Monitoring System ("System") consists of Ambio Wireless Connectors to send readings from off-the-shelf blood pressure and blood glucose meters; the Ambio Scale with built in wireless connectivity to send readings through the Ambio Gateway to the Ambio Care Portal. The Care Portal is used by patients and their caregivers ("Users") to view readings, set reminders to take meter readings and pills, set reading thresholds which will trigger alert messages and set who will get reminder and alert messages. Reading history can be printed or exported. Users can maintain an exercise log, food log and records of doctor visits and lab tests. Users can set goals and rewards for taking readings and for keeping readings in target ranges. A patient survey tool can be used to gather qualitative health information. The System also has a shared calendar and message board to coordinate among Users. General health information from accredited sources is also available.

The Ambio Remote Health Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The System does not alter the indicated use of the described blood pressure or blood glucose monitors.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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