K100133

510(k) Summary

Date:	May 25, 2010
Submitter:	AirStrip Technologies Inc. 3303 Oakwell Court #120 San Antonio, TX 78218
Contact Person:	Andy Miller Director, QA/RA Phone: 210-805-0444 Fax: 210-805-0446 E-Mail: andymiller@airstriptech.com
Trade Name:	AirStrip RPM
Common/Usual Name:	Doctor's Remote Data Viewing Software
Classification Reference:	Patient monitoring software has been classified as Class II, 870.2300. The classification panel 870: Cardiovascular. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for remote data viewing of cardiovascular data.
Predicate Devices:	GE Pocket Viewer (K061994) Cerner iBus (K093134)

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Device Description

AirStrip RPM is software that runs on devices capable of running Apple iPhone OS. It interfaces with third-party centralized monitoring systems that in turn gather data from patient monitors and other devices in the hospital. AirStrip RPM gives health care providers the ability to view near-real-time patient physiological data remotely.

Predicate Devices

The AirStrip RPM client is substantially equivalent to two FDA cleared devices. The GE Pocket Viewer (K061994) device provides the ability for the clinician to view real-time waveforms and other physiological patient data via Windows Mobile based PDA Smart Phones. Pocket Viewer works by retrieving patient data from the hospital monitoring system and providing that data to the end user's device via WiFi or cellular modem over the Internet. This is the same approach used for the AirStrip RPM product.

Physiological parameters that will be displayed by AirStrip RPM are collected through the Cerner iBus (K093134), which is listed as a predicate device to AirStrip RPM. These physiological parameters include ECG, invasive blood pressure, non-invasive blood pressure, heart rate, pulse oximetry and carbon dioxide. The complete list of physiological parameters captured is included in the Indications for Use below.

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In addition to physiological data, the iBus provides other patient data such as patient demographics and other non-physiological Electronic Medical Record (EMR) data. This data will also be made available through AirStrip RPM.

Indications for Use

AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians.

AirStrip RPM is intended to be used by clinicians for the following purposes:

- By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital
- To view the near real-time waveforms remotely
- To remotely review other standard or critical near real-time patient data from the monitored system
- To provide a request for remote consultation regarding a patient's waveform or other data

The AirStrip RPM software can display the following the physiologic data captured by other medical devices:

- ECG Waveform
- Blood Pressure Waveform
- O2 Waveform
- CO2 Waveform
- Heart Rate
- Respiratory Rate
- Oxygen Saturation
- Intracranial Pressure
- Central Venous Pressure
- Pulmonary Capillary Wedge Pressure
- Cardiac Index
- Cardiac Output
- Cerebral Perfusion Pressure
- Urine Output
- Urine/Stool Mix Output
- Systolic Blood Pressure Invasive
- Mean Arterial Pressure Invasive
- Diastolic Blood Pressure Invasive
- Systolic Blood Pressure Cuff
- Mean Arterial Pressure Cuff
- Diastolic Blood Pressure Cuff
- Vasoactive Infusions

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- Antiarrhythmics
- Sedation
- Paralytics
- Laboratory Data including
  - Blood Gas
  - Chemistry
  - Hematology
  - Coagulation
- Allergies
- Medications

Contraindications

AirStrip RPM software is intended for installation on cellular telephones and other wireless devices, and is not intended for use anywhere cellular telephones or wireless devices are prohibited.

Substantial Equivalence

AirStrip Technologies identified GE's Pocket Viewer and Cerner's iBus, formerly known as MDBus, as predicate devices to AirStrip RPM.

Pocket Viewer was originally submitted by Datex-Ohmeda and cleared by the FDA on October 29, 2003 through 510(k) K033078. A subsequent Pocket Viewer 510(k) submission submitted by GE was cleared by the FDA on January 20, 2006 through 510(k) number K052975. A third Pocket Viewer 510(k) submission submitted by GE was cleared by the FDA on August 11, 2006 through 510(k) number K061994. Further, the Pocket Viewer clearance is based on substantial equivalence to the Datex-Ohmeda Network and Central device which was cleared by the FDA on July 13, 2000.

Cerner's iBus was cleared by the FDA on November 27, 2009 through 510(k) K093134.

Device description and Substantial Equivalence Comparison between AirStrip RPM and the predicate devices, Pocket Viewer and iBus, are captured below.

Device Description and Comparison

AirStrip RPM is a software application that interfaces with centralized monitoring systems in hospitals to allow health care professionals the ability to view near real-time patient data remotely. The AirStrip RPM platform is designed around a reusable architecture allowing display of any waveform or other patient data through the creation of an adapter to allow for data exchange with patient monitoring systems.

The AirStrip RPM client is substantially equivalent to the FDA cleared GE Pocket Viewer device which received initial FDA clearance as a Datex-Ohmeda product on October 29, 2003 through 510(k) K033078. The most recent FDA clearance for Pocket Viewer was granted in 510(k) number K061994 on August 11, 2006. GE Pocket Viewer provides the ability for the clinician to view real-time waveforms and other physiological patient data via Windows Mobile based PDA

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Smart Phones. Pocket Viewer works by retrieving patient data from the hospital monitoring system and providing that data to the end user's device via WiFi or cellular modem over the Internet. This is the same approach used for the AirStrip RPM product.

The initial adapter proposed in this submission is the FDA-cleared Cerner CareAware iBus, also known as MDBus, which was cleared through 510(k) K093134 on November 27, 2009. Physiological parameters that will be displayed include those physiological parameters collected through the iBus interface from FDA-cleared patient monitors. These physiological parameters include such parameters as ECG, invasive blood pressure, non-invasive blood pressure, heart rate, temperature, cardiac output, respiration, pulse oximetry and carbon dioxide.

In addition to the physiological data that iBus provides, other patient data such as patient demographics data and Electronic Medical Record (EMR) data are also available within the application and made available to AirStrip RPM.

Substantial Equivalence - Client

GE's Pocket Viewer device provides the ability for clinicians to remotely view patient data on a Windows Mobile handheld PDA. It displays patient physiological data and waveforms based on data that is made available via the Datex-Ohmeda Network or Unity network. Based on the Pocket Viewer brochure, the data that can be displayed includes waveforms and vital signs. Based on the Pocket Viewer User's Guide, the type of waveforms that are available include ECG, EEG, O2, and CO2. These waveforms are captured as selection options on pages 47-48 of the User's Guide. The data that the Pocket Viewer is cleared to display is based on the data that the Web Viewer was cleared to display through 510(k) submission K013387 dated January 8, 2002 as it served as the predicate device. The predicate device for the Web Viewer is the Datex-Ohmeda S/5 Network and Central device which was cleared through 510(k) K000647 dated July 13, 2000. These two clearance letters are included in Appendix B. In the device description section of the 510(k) clearance letter for of the Datex-Ohmeda Network and Central device, one of the monitors listed is the Cardiocap 5 Critical Care monitor. The brochure for the Datex-Ohmeda Cardiocap 5 monitor describes the types of waveforms that are displayed on the monitor including ECG. The table below captures the relationship between the predicate devices and our proposed device regarding the ability to display ECG waveform data. It is clear from this table that the GE Pocket Viewer device is cleared to display ECG waveform data and therefore can serve as a predicate device to the AirStrip RPM client for displaying ECG waveform data.

Datex-Ohmeda Cardiocap 5 Monitor	Datex-Ohmeda S/5 Network and Central	Datex-Ohmeda Web Viewer	GE Pocket Viewer	AirStrip RPM
510(k): K992323	510(k): K000647	510(k): K013387, K023497	510(k): K033078, K061994	Proposed
ECG Waveform display	Includes ability to display waveforms from the Cardiocap 5 monitor.	Provides same ability as S/5 Network and Central to view waveform data which would include ECG.	Provides same ability as Web Viewer to view waveform data which would include ECG.	Provides ability to view ECG waveforms through interface with iBus
	Predicate device for Web Viewer	Predicate device for Pocket Viewer	Predicate device for AirStrip RPM 3.1	

Table 1- ECG Waveform Clearance in Predicate Device

The client portion of the AirStrip RPM software application has the following similarities to GE's Pocket Viewer which previously received 510(k) clearance:

- has the same indicated use,
- has the same target population,
- uses the same operating principle,
- uses the same communication methods and protocols,
- uses the same data source location,
- uses the same data presentation type, and
- incorporates the same basic software design.

Substantial equivalence of operating function is detailed in the table below:

Function Specification	GE Pocket Viewer (FDA Cleared)	AirStrip RPM (Proposed)
Function – Indications for Use	Smart Client application that allows users at remote locations (anywhere there is internet access) to view patient information including physiological data, waveforms and other EMR related data.	Smart Client application that allows users at remote locations (anywhere there is internet access) to view patient information including physiological data, waveforms and other EMR related data.
Target Population	Clinicians	Clinicians
Materials	Software application and configured PDA	Software application and configured PDA
Internet Communication	Secure Sockets Layer (SSL) via HTTPS	Secure Sockets Layer (SSL) via HTTPS
Communication Methods	Cellular Modem, Wi-Fi	Cellular Modem, Wi-Fi
Data Source Location	Hospital	Hospital
Security Administration	Yes	Yes
Where Used	Anywhere the clinician has remote internet access	Anywhere the clinician has remote internet access
Operating Systems	Microsoft Windows CE.NET family of operating systems	iPhone OS
Presentation of Data	Smart Client	Smart Client
Ability to view near Real-time Data	Yes	Yes

Table 2- Substantial Equivalence Operation Functional Comparison

Substantial Equivalence - Adapter

Cerner's CareAware iBus is the adapter through which AirStrip RPM will capture patient data. CareAware iBus was cleared through the FDA on November 27, 2009 through 510(k) K093134.

CareAware iBus provides the ability to gather data from connected medical devices by capturing the data from the connected device and making it available the hospital's healthcare IT system. The proposed AirStrip RPM solution provides the ability to gather data from connected medical devices by capturing the data from the connected device and making it available to the AirStrip RPM server via the CareAware iBus adapter.

The patient monitoring data presented in the AirStrip RPM software application has the following similarities to the Cerner CareAware iBus which previously received 510(k) concurrence through 510(k) K093134 dated November 27, 2009:

- has the same operating principle,
- has the same target population,
- uses the same type of data sources.

Function Specification	Cerner CareAware iBus (FDA Cleared)	AirStrip RPM (Proposed)
Function – Indications for Use	Capture patient data from externally connected devices and make available to networked clinical information systems	Capture patient data from clinical information system and display on remote devices
Target Population	Clinicians	Clinicians
Data Source Location	Hospital	Hospital
Data Types	Patient physiological data including blood pressure, cardiac monitor, breathing frequency, oxygen uptake	Patient physiological data including blood pressure, cardiac monitor, breathing frequency, oxygen uptake
Security Administration	Yes	Yes
Where Used	Anywhere the physician has Clinical Information System access	Anywhere the physician has remote internet access
Presentation of Data	Networked Clinical Information System	Smart Client
Ability to View Near Real-time Data	Yes	Yes

Table 4 - Substantial Equivalence Comparison

The table below lists the data physiological and non-physiological data elements provided by FDA-cleared Cerner iBus, the level of concern of each element, and which of these are displayed by the FDA-cleared Pocket Viewer and proposed AirStrip RPM.

Data Element Provided by Cerner iBus (FDA Cleared)	Level of Concern	GE Pocket Viewer (FDA Cleared)	AirStrip RPM (Proposed)
Logon	High	Displays	Displays
Patient Census	High	Displays	Displays
Automatically Gathered (Monitored) Waveform Physiological Data with Scrolling			
ECG	High	Displays	Displays
Blood Pressure	High	Displays	Displays
O2	High	Displays	Displays
CO2	High	Displays	Displays
Automatically Gathered (Monitored) Near-Real-Time Patient Physiological Data			
Heart Rate	High	Displays	Displays
Respiratory Rate	High	Displays	Displays
Oxygen Saturation	High	Displays	Displays
Intracranial Pressure	High	Displays	Displays
Central Venous Pressure	High	Displays	Displays
Pulmonary Capillary Wedge Pressure	High	Displays	Displays
Cardiac Index	High	Displays	Displays
Cardiac Output	High	Displays	Displays
Cerebral Perfusion Pressure	High	Displays	Displays
Systolic Blood Pressure Cuff	High	Displays	Displays
Mean Blood Pressure Cuff	High	Displays	Displays
Diastolic Blood Pressure Cuff	High	Displays	Displays
Systolic Blood Pressure Invasive	High	Displays	Displays
Mean Blood Pressure Invasive	High	Displays	Displays
Diastolic Blood Pressure Invasive	High	Displays	Displays
Temperature	High	Displays	Displays
Manually Gathered (Non-Monitored) Patient Physiological Data			
Urine Output	Low	Does Not Display	Displays
Urine/Stool Mix Output	Low	Does Not Display	Displays
Vasoactive Infusions	Low	Does Not Display	Displays
Antiarryhthmics	Low	Does Not Display	Displays
Sedation	Low	Does Not Display	Displays
Paralytics	Low	Does Not Display	Displays
Manually Gathered (Non-Monitored) Patient Laboratory Data			
Blood Gas	Low	Does Not Display	Displays
Chemistry	Low	Does Not Display	Displays
Hematology	Low	Does Not Display	Displays
Coagulation	Low	Does Not Display	Displays
Other Manually Gathered (Non-Monitored) Patient Information			
Patient Allergies	Low	Does Not Display	Displays
Patient Medications	Low	Does Not Display	Displays
Patient Demographics	Low	Does Not Display	Displays

Table 3 - Equivalent Data Function Comparison

As the table above illustrates, GE Pocket Viewer does not currently display every data point AirStrip RPM displays. However, GE Pocket Viewer does display every automatically gathered – or monitored – physiologic data point AirStrip RPM proposes to display. These data points are

considered to be of a higher level of concern since they are compiled without human intervention.

AirStrip Technologies conducted verification testing of all data points listed. In this test, known datasets were gathered from Cerner iBus and displayed on AirStrip RPM. These datasets included all data points proposed in AirStrip RPM; all waveforms, all monitored data, all manual data, including patient demographics. In all cases, AirStrip RPM was able to display data points with complete accuracy. The verification test report is provided as Appendix SSSSS.

Testing and Labeling

Since a comparison of the descriptive characteristics of the proposed and predicate devices may not be sufficient to precisely assure safety and effectiveness, AirStrip Technologies used "Radio-Frequency Wireless Technology in Medical Guidance: Draft Guidance for Industry and FDA Staff" as a guide to determine what testing should be done on AirStrip RPM and to determine what additional labeling should be included with the product.

Testing

AirStrip RPM is only intended for installation on Apple iPhone, iPod Touch or iPad. AirStrip Technologies reviewed testing conducted by the Original Equipment Manufacturer (OEM), Apple Computer, on these devices. Additional testing was performed on AirStrip RPM when needed.

Other guidance used:

- ANSI/AAMI/IEC 60601-1-2: Medical electrical equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO/TR 2130: Health informatics – Use of mobile wireless communication and computing technology in healthcare facilities – Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices
- ANSI C63.18-1997: American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters

AirStrip Technologies testing included:

- AirStrip RPM Software Waveform Functional Testing
- AirStrip RPM Software Non-Waveform Functional Testing
- AirStrip RPM In-Band Interference and Wireless Network Coexistence Testing
- AirStrip RPM On-Site Ad Hoc Electromagnetic Immunity Testing

AirStrip RPM was found to have met all testing requirements.

Labeling

AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. It is intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitoring devices from which it obtains its data. Further, since AirStrip RPM is installed on a cellular telephone or other wireless device, it is possible that radiated emissions from other medical devices could interfere with its operation. For this reason, AirStrip RPM is not intended for use in hospitals. These contraindications are clearly explained in end-user training and product documentation. Further, a warning message is prominently display to the end user on the AirStrip RPM logon screen.

Manufacturer's guidance is also included in AirStrip RPM documentation. This guidance was developed using IEC 60601-1-2 as a template and instructs the user on how to minimize risk of using AirStrip RPM in areas with medical equipment and other sources of radiated and conducted electromagnetic disturbances. AirStrip Technologies also provides clients with guidance on how to test AirStrip RPM for use in their environment based on recognized testing standards.

Conclusion

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetics Act and various guidance documents issued by the Center for Device and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL 2 3 2010

AirStrip Technologies, LP
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th St, NW
Buffalo MN 55313

Re: K100133
Trade/Device Name: AirStrip RPM 3.1
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MWI
Dated: July 8, 2010
Received: July 9, 2010

Dear Mr. Job:

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,

Donna R. Vickers

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) K100133

Device Name AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing software

Indications for Use

AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians.

AirStrip RPM is intended to be used by clinicians for the following purposes:

- By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital
- To view the near real-time waveforms remotely
- To remotely review other standard or critical near real-time patient data from the monitored system
- To provide a request for remote consultation regarding a patient's waveform or other data

The AirStrip RPM software can display the following the physiologic data captured by other medical devices:

- Heart Rate Monitored
- Respiratory Rate
- Oxygen Saturation
- Intracranial Pressure
- Central Venous Pressure
- Pulmonary Capillary Wedge Pressure

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Ockman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100133

- Cardiac Index
- Cardiac Output
- Cerebral Perfusion Pressure
- Urine Output
- Urine/Stool Mix Output
- Systolic Blood Pressure Invasive
- Mean Arterial Pressure Invasive
- Diastolic Blood Pressure Invasive
- Systolic Blood Pressure Cuff
- Mean Arterial Pressure Cuff
- Diastolic Blood Pressure Cuff
- Vasoactive Infusions
- Antiarrhythmics
- Sedation
- Paralytics
- Laboratory Data including
  - Blood Gas
  - Chemistry
  - Hematology
  - Coagulation
- Allergies
- Medications

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

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