September 11, 2018

AirStrip Technologies, Inc.
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K182226
Trade/Device Name: AirStrip RPM InvisionHeart Adapter
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: August 14, 2018
Received: August 16, 2018

Dear Mark 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S5

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182226

Device Name
AirStrip RPM InvisionHeart Adapter

Indications for Use *(Describe)*
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 waveform 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 physiologic data captured by other medical devices:
●ECG Waveform
●Heart Rate Monitored
●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
●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. AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. AirStrip RPM 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

AirStrip RPM InvisionHeart Adapter 510(k) Summary

Submitter Information [21 CFR 807.929(a)(1)]	
Name	AirStrip Technologies
Address	335 E. Sonterra Blvd., Suite 200 San Antonio, TX 78258
Phone number	+1 210 805 0444
Fax number	+1 210 805 0446
Establishment Registration Number	Establishment Registration Number: 3006104191
Name of contact person	Kirk Johnson
Date prepared	September 4, 2018
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	AirStrip RPM InvisionHeart Adapter
Common or usual name	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Classification name	Remote Patient Monitoring has been classified as Class II, 870.2300, MWI. The classification panel 870: Cardiovascular.
Classification panel	Cardiovascular
Regulation	870.2300
Product Code(s)	MWI
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	The predicate device is the AirStrip RPM Epiphany Adapter, K133450, cleared February 14, 2014.
Device description [21 CFR 807.92(a)(4)]	AirStrip RPM InvisionHeart Adapter The AirStrip RPM InvisionHeart Adapter is a software application that interfaces with the InvisionECG System in hospitals to allow health care professionals the ability to view near real-time patient data remotely. AirStrip RPM works by retrieving patient data from the InvisionECG System monitoring system and providing that data to the end user's device via Wi-Fi or cellular modem over the Internet. InvisionECG System The InvisionECG System (cleared under K143436; InvisionHeart Inc.) is a mobile solution for capturing and managing 12-lead ECGs, including the ability to read and visually compare, confirm, report and store diagnostic quality electrocardiograms. This is all done on a browser-based, secure, healthcare IT platform which provides access to ECGs anywhere and anytime an authorized healthcare professional has web access via an appropriate browser. The cleared Indications For Use states "The InvisionECG System is

	intended to acquire, display and record electrocardiographic information from adult and pediatric patients. The InvisionECG System is intended to be used in a clinical or home environment by trained healthcare professionals." Additional information may be obtained at www.invisionheart.com.
Indications for use [21 CFR 807.92(a)(5)]	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 • Heart Rate Monitored • 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 • 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. AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. AirStrip RPM 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.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]

Function Specification	AirStrip RPM InvisionHeart Adapter (Proposed)	AirStrip RPM Epiphany Adapter 510(k) #K133450
Purpose	Provides ability to view patient physiological waveforms and other	Provides ability to view physiological waveforms and other data remotely

	data remotely through interface with InvisionECG.	through interface with Epiphany Cardiology.
Function – Indications for Use	Smart Client application that allows users at remote locations (anywhere there is internet access) to view patient information in near real time 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 in near real time including physiological data, waveforms and other EMR related data.
Target Population	Clinicians (users) Target population (clinical patients) are anyone using a monitoring device for cardio. The use of this device is not controlled by patient group. Instead it is controlled by diagnosis and the use of a specific cardio monitoring device. The software and the portal can only differentiate between "source" of the waveform information ("adapters") as the software only reads and repeats the information for display remotely. Invision Heart device is the source of data. The Electrocardiogram cannot and does not differentiate between patient groups, therefore, the monitoring of any patient using the Epiphany Adapter (elderly or pediatric) is within the scope of this device. Therefore Airstrip which is only reproducing the information from InvisionHeart also cannot differentiate between patient populations using the electrocadiogram.	Clinicians (users) Target population (clinical patients) are anyone using a monitoring device for cardio. The use of this device is not controlled by patient group. Instead it is controlled by diagnosis and the use of a specific cardio monitoring device. The software and the portal can only differentiate between "source" of the waveform information ("adapters") as the software only reads and repeats the information for display remotely. Invision Heart device is the source of data. The Electrocardiogram cannot and does not differentiate between patient groups, therefore, the monitoring of any patient using the Epiphany Adapter (elderly or pediatric) is within the scope of this device. Therefore Airstrip which is only reproducing the information from Epiphany Adapter also cannot differentiate between patient populations using the electrocardiogram.
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

System Technology	File Based Service Web based service and file based service are two methods of picking up a snapshot of ECG data from the collecting medical device (in this application Invisionheart) for viewing through the AirStrip software on mobile devices. Whether gathering the data from a web service call (e.g. K100133) or a file based system (e.g. K110503, K133450/Epiphany Adapter or the proposed K182226/ InvisionHeart Adapter) each is a mechanism for capturing the snapshot to be used by AirStrip RPM. Once captured by AirStrip RPM, the information is treated the same and the data in the file is parsed for the information required. There is no dependency on the method of capture for how the data is parsed. For the web based approach, a query is made and data is gathered from that query, as compared to the file based method where AirStrip is pointed to a particular directory where the file resides and AirStrip picks it up. Once in Airstrip RPM, both methods are processed the same way inside of AirStrip and then transmitted to mobile users. There is no dependency on the original system file so once the file is successfully parsed, the system file is then removed from the specified directory by AirStrip to prevent repetitive processing.	File Based Service Web based service and file based service are two methods of picking up a snapshot of ECG data from the collecting medical device (in this application Invisionheart) for viewing through the AirStrip software on mobile devices. Whether gathering the data from a web service call (e.g. K100133) or a file based system (e.g. K110503, K133450/Epiphany Adapter) each is a mechanism for capturing the snapshot to be used by AirStrip RPM. Once captured by AirStrip RPM, the information is treated the same and the data in the file is parsed for the information required. There is no dependency on the method of capture for how the data is parsed. For the web based approach, a query is made and data is gathered from that query, as compared to the file based method where AirStrip is pointed to a particular directory where the file resides and AirStrip picks it up. Once in Airstrip RPM, both methods are processed the same way inside of AirStrip and then transmitted to mobile users. There is no dependency on the original system file so once the file is successfully parsed, the system file is then removed from the specified directory by AirStrip to prevent repetitive processing.
Security Administration	Yes	Yes
Operating Environment	Anywhere the clinician has remote Internet access for iOS or Android device and use is not prohibited Hospital data center for server	Anywhere the clinician has remote Internet access for iOS or Android device and use is not prohibited Hospital data center for server
Programming Languages	Apple Objective C and Swift on client Android Java and Kotlin Microsoft Windows .NET on server	Apple Objective C on client Android Microsoft Windows .NET on server

Operating Systems	Apple iPhone OS on client Android OS on client Microsoft Windows Server on servers	Apple iPhone OS on client Android OS on client Microsoft Windows Server on servers
Database System	Microsoft SQL Server	Microsoft SQL Server
Hardware Platform	Apple iPhone OS devices for client Android OS devices for client Microsoft Windows Server compatible server computers	Apple iPhone OS devices for client Android OS devices for client Microsoft Windows Server compatible server computers
Presentation of Data	Smart Client	Smart Client
Ability to view near Real-time Data	Yes	Yes

Performance Data [21 CFR 807.92(b)]

Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

The InvisionHeart Adapter Software is a moderate level of concern. The software was designed and developed adhering to in-house design and development process. The software underwent verification and validation testing and was in the form of combined integration and system testing as well as final regression testing.

The software testing and documentation is in accordance with internal requirements and the following FDA Guidance documents:

- General principles of software validation, Final Guidance for Industry and FDA Staff; January 11, 2002
- Off –The-Shelf Software Use In Medical Devices; September 09, 1999
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; October 02, 2014

The adapter is in accordance with the following standards:
The InvisionHeart Adapter accepts and transmits as a viewer the DICOM file information compliant with DICOM SOP 1.2.840.10008.5.1.4.1.1.9.1.1 *12-lead ECG Waveform Storage.* See https://www.dicomlibrary.com/dicom/sop/

ISO 14971:2007 Medical devices – Applications of risk management to medical devices

Test results indicate that the InvisionHeart Adapter Software complies with its predetermined specifications and the applicable guidance documents.

Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]

This section is not applicable to this submission. Clinical Data are not included.

InvisionHeart ECG System (by Nuline/InvisionHeart) Standard Compliance

The InvisionHeart ECG System is compliant to 60601-2-25:2011 (Medical electrical equipment–Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs). For

additional information refer to link https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143436.pdf.
Conclusions drawn [21 CFR 807.92(b)(3)]
Based on the results of testing, the AirStrip RPM InvisionHeart Adapter is substantially equivalent to the AirStrip RPM Epiphany predicate device.