December 9, 2021

AirStrip Technologies, Inc.
JF Lancelot
Chief Technology Innovation Officer
2915 West Bitters Road, Suite 215
San Antonio, Texas 78248

Re: K211949
Trade/Device Name: AirStrip ONE Web Client with Alarm Communication Management (ACM)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: November 9, 2021
Received: November 10, 2021

Dear JF Lancelot:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211949

Device Name
AirStrip ONE Web Client with Alarm Communication Management (ACM)

Indications for Use *(Describe)*
AirStrip ONE Web Client with ACM is intended to allow clinicians to capture and display waveforms (such as ECG, SpO2, ART), discrete parameters, patient demographics, alarms, and other information from medical devices on a desktop device. This software is intended as a diagnostic aid to provide access for professional staff to view patient clinical data when the professional cannot observe the source system directly. AirStrip ONE Web Client with ACM does not store Protected Healthcare Information on the device accessing the data. Data available on the web viewer is in "near real time" and is displayed to show a full range of clinical data available, even when the data sources are obtained from different devices.

AirStrip ONE Web Client with ACM gathers data from the medical devices that are connected to the patient. AirStrip ONE Web Client with ACM is not directly connected to the individual, but to a networked medical device receiving data, and connects that data to individuals by medical record number or defined patient ID. AirStrip ONE Web Client with ACM is intended to be used by clinicians for the following purposes:

- To visualize physiological data using a web viewer to assess clinical status of a patient when the source system cannot be observed directly by the clinician.
- To view the near real-time and historic waveforms.
- To view other near real-time patient data from a monitored system.
- To provide a request for remote consultation regarding a patient's waveform or other data.
- To send electronic images of the cardiac rhythm to the medical record.
- To allow clinicians to manage secondary alarm transmission by suppressing non-critical alarms.

AirStrip ONE Web Client with ACM is appropriate for use in pediatric (0-21 years), adult and geriatric populations, as the networked medical devices AirStrip collects data from are already cleared for these populations. AirStrip ONE Web Client with ACM software can display the following physiologic parameters and waveforms captured by other cleared medical devices:

- ECG Waveform
- Heart Rate
- Respiratory Rate
- Oxygen Saturation
- Intracranial Pressure
- Central Venous Pressure
- Pulmonary Capillary Wedge Pressure
- Pulmonary Artery Pressure
- Cardiac Index
- Cardiac Output
- Cerebral Perfusion Pressure
- Temperature
- Temperature Source
  - o Bispectral index (BIS)
  - o Umbilical Artery
  - o Body Weight
- 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
- Ventilators
- Allergies
- IV Fluid Delivery Rate
- IV Medication Dose
- Pulse Rate
- Bispectral Parameters
- Monitored Events
- Right Atrial Pressure
- Left Atrial Pressure
- Laboratory Data, including
  - o Blood Gas
  - o Chemistry
  - o Hematology
  - o Coagulation
- Hemodynamic Calculated Values
- Medications
- IV Volume Infused
- ETCO2
- Fractional Inspired Concentration O2, CO2
- Case Consumption Liquid Medications
- Case Consumption Respiratory Gas

Contraindications: There are no contraindications.

Warning: AirStrip ONE Web with ACM is an adjunct to and not a replacement for direct viewing of the monitoring medical device(s).

Precautions: AirStrip ONE Web with ACM requires an internet or cellular connection to provide data. AirStrip ONE Web with ACM is not intended for use where cellular telephones or other wireless devices are prohibited.

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.

510(k) Summary
(in accordance with 21 CFR §807.92)

Submission Date:	09 November 2021
Submitter:	AirStrip Technologies, Inc. 2915 West Bitters Road, Suite 215 San Antonio, TX 78248 United States of America
Submitter and Application Correspondent	Mr. JF Lancelot Chief Technology Innovation Officer Phone: +1 (858) 848-5556 Email: jflancelot@airstrip.com
Manufacturing Site:	AirStrip Technologies, Inc. 2915 West Bitters Road, Suite 215 San Antonio, TX 78248 United States of America
Trade Name:	AirStrip ONE Web Client with Alarm Communication Management (ACM)
Common Name:	Physiological Monitors Network and Communication System
Classification Name:	Physiological Monitors Network and Communication System
Classification Regulation:	21 CFR §870.2300
Product Code:	MSX

Substantially Equivalent Devices:	*New AirStrip Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	AirStrip ONE Web Client with Alarm Communication Management (ACM)	K160862	AirStrip Technologies, Inc. / AirStrip ONE Web Client

510(k) Summary
(in accordance with 21 CFR §807.92)

Device Description:

The AirStrip Technologies, Inc. (AirStrip) ONE Web Client, the predicate device being modified to include the AirStrip Alarm Communication Management (ACM), provides visualization of monitoring data, waveforms, and events for clinicians who are away from the bedside to support and enhance their collaboration with other care team members who are with the patient.

All data, waveforms and events displayed by AirStrip ONE Web Client are generated by primary monitors, not by AirStrip ONE Web Client. Events that triggered alarms by the primary monitor system populate in AirStrip ONE Web Client in near real time so a remote (i.e. not at bedside) clinician can review these items while they are collaborating with other care team members.

The AirStrip ONE Web Client remote patient monitoring is a visualization and collaboration aid. It allows for the display of waveform, monitoring data, and events that triggered primary patient monitor alarms without itself originating alarms. The clinical use of AirStrip ONE Web Client presupposes nurses or other clinicians will be at the hospital, either at the bedside or a near-by monitoring station.

The AirStrip ONE Web Client with Alarm Communication Management (ACM) module is a "rules engine" module that, when used in conjunction with, and as a part of, the existing AirStrip ONE Web Client to gather alarms from various alarm sources, processes the alarms through a rules configuration tool (the proposed device) using clinical rules established by the customer, typically a healthcare institution, to filter and distribute those alarms to a third-party server connected to mobile devices carried by healthcare providers. The display device stays in a notification state until the healthcare provider dispositions the alarm.

510(k) Summary
(in accordance with 21 CFR §807.92)

Intended Use:

AirStrip ONE Web Client with ACM is intended to allow clinicians to capture and display waveforms (such as ECG, SpO2, ART), discrete parameters, patient demographics, alarms, and other information from medical devices on a desktop device. This software is intended as a diagnostic aid to provide access for professional staff to view patient clinical data when the professional cannot observe the source system directly. AirStrip ONE Web Client with ACM does not store Protected Healthcare Information on the device accessing the data. Data available on the web viewer is in "near real time" and is displayed to show a full range of clinical data available, even when the data sources are obtained from different devices.

AirStrip ONE Web Client with ACM gathers data from the medical devices that are connected to the patient. AirStrip ONE Web Client with ACM is not directly connected to the individual, but to a networked medical device receiving data, and connects that data to individuals by medical record number or defined patient ID. AirStrip ONE Web Client with ACM is intended to be used by clinicians for the following purposes:

- To visualize physiological data using a web viewer to assess clinical status of a patient when the source system cannot be observed directly by the clinician.
- To view the near real-time and historic waveforms.
- To view other near real-time patient data from a monitored system.
- To provide a request for remote consultation regarding a patient's waveform or other data.
- To send electronic images of the cardiac rhythm to the medical record.
- To allow clinicians to manage secondary alarm transmission by suppressing non-critical alarms.

AirStrip ONE Web Client with ACM is appropriate for use in pediatric (0-21 years), adult and geriatric populations, as the networked medical devices AirStrip collects data from are already cleared for these populations. AirStrip ONE Web Client with ACM software can display the following physiologic parameters and waveforms captured by other cleared medical devices:

- ECG Waveform
- Heart Rate
- Respiratory Rate
- Oxygen Saturation
- Intracranial Pressure
- Central Venous Pressure
- Pulmonary Capillary Wedge Pressure
- Pulmonary Artery Pressure
- Cardiac Index
- Cardiac Output

- Cerebral Perfusion Pressure
- Temperature
- Temperature Source
  - Bispectral index (BIS)
  - Umbilical Artery
  - Body Weight
- 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
- Ventilators
- Allergies
- IV Fluid Delivery Rate
- IV Medication Dose
- Pulse Rate
- Bispectral Parameters
- Monitored Events
- Right Atrial Pressure
- Left Atrial Pressure
- Laboratory Data, including
  - Blood Gas
  - Chemistry
  - Hematology
  - Coagulation
- Hemodynamic Calculated Values
- Medications
- IV Volume Infused
- $ETCO_2$
- Fractional Inspired Concentration O_2, CO_2
- Case Consumption Liquid Medications
- Case Consumption Respiratory Gas

Contraindications: There are no contraindications.

Warning: AirStrip ONE Web with ACM is an adjunct to and not a replacement for direct viewing of the monitoring medical device(s).

Precautions: AirStrip ONE Web with ACM requires an internet or cellular connection to provide data. AirStrip ONE Web with ACM is not intended for use where cellular telephones or other wireless devices are prohibited.

510(k) Summary
(in accordance with 21 CFR §807.92)

Predicate Device Comparison:

AirStrip ONE Web Client with Alarm Communication Management (ACM) employs the same indications for use and technological characteristics as the predicate device.

Intended Use (IU) and Indications for Use (IFU) Discussion

The predicate device, AirStrip ONE Web Client has the following Intended Use and IFU statement:

AirStrip ONE Web Client 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 this device. This device captures this information from these other systems and displays it for clinicians.

This device is intended to be used by clinicians for the following purposes:

- To view 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.

This device 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
- Systolic Blood Pressure Invasive
- Mean Arterial Pressure Invasive
- Diastolic Blood Pressure Invasive
- Systolic Blood Pressure Cuff
- Mean Arterial Pressure Cuff
- Diastolic Blood Pressure Cuff

Contraindications

This device is intended for use by clinicians when they cannot be at the hospital. This device 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.

There are three (3) types of modifications made to the AirStrip ONE Web Client with ACM compared to the predicate device's IU/IFU statement:

1. Modifications made to clarify the predicate device's IU/IFU statement. These modifications do not modify the intended use or IFU of the AirStrip ONE Web Client predicate device or change the risk profile of the device.
2. Modifications made to incorporate the new ACM feature within the IU/IFU statement. This includes the addition of the term "with ACM" behind the product name, and the addition of the following statement:
   - To allow clinicians to manage secondary alarm transmission by suppressing non-critical alarms.

   These modifications do not modify the intended use or IFU of the AirStrip ONE Web Client with ACM or the predicate device or change the risk profile of either the predicate or proposed device.
3. Modifications to the IU/IFU statement to clarify that the information previously identified as contraindications is now either included in the IU/IFU statement itself or as a warning or precaution.

Therefore, the IU/IFU statements representing the predicate device and proposed device are considered substantially equivalent.

Technology Discussion

The technology of the AirStrip ONE Web Client predicate device and the AirStrip ONE Web Client with ACM proposed device is the same.

The AirStrip ONE Web Client predicate device was not modified. The ACM feature is new software used in conjunction with the AirStrip ONE Web Client that incorporates a feature allowing the alarms and events received from the primary source monitoring device to be filtered according to customer-determined needs and/or delayed or suppressed.

The only difference between the two devices is that the AirStrip ONE Web Client does not include the ACM feature and the AirStrip ONE Web Client with ACM includes the ACM feature.

Therefore, the technology used in the predicate device and proposed device are considered substantially equivalent.

510(k) Summary
(in accordance with 21 CFR §807.92)

Summary of Performance Testing:

Software

AirStrip ONE Web Client with ACM software was designed and developed according to a robust software development process and was rigorously verified and validated.

Software information is provided in accordance with internal requirements and the following guidance documents and standards:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05.*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99.*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 02 Oct 14.*
- *Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) software, 14 Jan 05.*
- *Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.*
- *IEC 62304: 2015, Medical device software – Software life cycle processes.*
- *ISO 14971: 2007, Medical devices – Application of risk management to medical devices.*
- *ISO /IEC 27001: 2013, Information technology – Security techniques – Information security management systems – Requirements.*

Test results indicate that AirStrip ONE Web Client with ACM complies with its predetermined specifications and the guidance documents.

Performance Testing – Bench

AirStrip ONE Web Client with ACM was tested for performance in accordance with internal requirements including:

- *Risk Control Measure Verification.*
- *ISO /IEC 27001: 2013 Certification.*
- *Dynamic Code Analysis.*
- *Static Code Analysis and Vulnerability Scan.*
- *Network Test Scan.*
- *Interoperability Verification.*

Verification results indicated that AirStrip ONE Web Client with ACM complies with internal requirements.

510(k) Summary
(in accordance with 21 CFR §807.92)

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to AirStrip ONE Web Client with ACM. The results of these activities demonstrate that AirStrip ONE Web Client with ACM is as safe and as effective in comparison to the predicate device when used in accordance with its intended use and labeling.

Therefore, AirStrip ONE Web Client with ACM is considered substantially equivalent to the predicate device.