



September 19, 2016

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Airstrip Technologies, Inc.
% Curtis Egan
Quality, Regulator and Design Engineer
Certified Compliance Solutions, Inc.
11665 Avena Place #203
San Diego, California 92128-2504

Re: K160862

Trade/Device Name: Airstrip ONE Web Client
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: August 17, 2016
Received: August 18, 2016

Dear Curtis Egan:

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 contact the Division of Industry and Consumer Education 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>. 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 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 Industry and Consumer Education 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
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K160862

Device Name
AirStrip One Web Client

Indications for Use (Describe)

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 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

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

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.”