



December 15, 2017

Mediana Co., Ltd.  
% Charlie Mack  
President  
International Regulatory Consultants  
7808 Rush Creek Drive  
Pasco, Washington 99301

Re: K170497

Trade/Device Name: V10  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: Class II  
Product Code: DXN, DQA, FLL  
Dated: October 24, 2017  
Received: November 17, 2017

Dear Charlie Mack:

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.

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.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for

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)  
K170497

Device Name  
V10

### Indications for Use (Describe)

The V10 is intended to be used to monitor noninvasive blood pressure (NIBP) - systolic, diastolic and mean arterial pressures, functional arterial oxygen saturation (SpO2), pulse rate (PR), temperature (Temp) for adult, pediatric and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist. The V10 is suitable for continuous operation.

Note: Hospital use typically includes such as general care floors, operating rooms, special procedure areas, intensive and critical care area, within the hospital. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgical centers, and sub acute care centers.

Note: The medically skilled and trained user can be clinicians like doctors and nurses who know how to take and interpret a patient's vital signs. These clinicians must take direct responsibility for the patient's life. This can include care-givers or medically trained interpreters who are authorized under the appropriate clinical facility procedures to support patient care. Any inappropriate setting, especially the alarm limit or alarm notification settings, can lead to a hazardous situation that injures the patient, harms the patient, or threatens the patient's life. This equipment should only be operated by trained users who can adjust the settings of the vital signs monitor.

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.

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## 510(k) Summary of Safety and Effectiveness

### Submitter

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Tel) +82-33-742-5400 Fax) +82-33-742-5483

Company Contact: Ju-yeon, Song

Date Summary Prepared: October 20, 2017

### Device Name

Trade Name: V10  
Common Name: Vital Signs Monitor  
Classification Name: NIBP measurement system (21CFR870.1130), also contains non-invasive pulse oximetry, SpO<sub>2</sub> (21CFR870.2700) and clinical electronic thermometer (21CFR880.2910)  
Classification: Class II  
Product Code: DXN, DQA, FLL

### Predicate Devices (Legally Marketed Devices)

The predicate device for the V10 are:

- **Mediana Co., Ltd.** Vital Signs Monitors, V10  
Cleared by FDA through 510(k) No. **K152659**

### Device Description

The V10 vital signs monitor is to monitor non-invasive blood pressure, pulse rate, non-invasive functional oxygen saturation of arterial hemoglobin for adult, pediatric and neonate patients and body temperature for adult and pediatric patients in general hospital and alternate care facilities by medically trained personnel. This monitor is available for sale only upon the order of a physician or licensed health care professional.

The Mediana V10 vital signs monitor is a lightweight and compact device (249 × 211 × 154 (mm) (W×H×D) and 3.0 kg) powered by AC mains (100-240VAC, 50Hz/60Hz) and also powered by internal battery. The monitor provides patient data and monitoring status on 7-segment LED displays.

## Intended Use

The V10 is intended to be used to monitor noninvasive blood pressure (NIBP) - systolic, diastolic and mean arterial pressures, functional arterial oxygen saturation (SpO<sub>2</sub>), pulse rate (PR), temperature (Temp) for adult, pediatric and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist. The V10 is suitable for continuous operation.

Note: Hospital use typically includes such as general care floors, operating rooms, special procedure areas, intensive and critical care area, within the hospital. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgical centers, and sub acute care centers.

Note: The medically skilled and trained user can be clinicians like doctors and nurses who know how to take and interpret a patient's vital signs. These clinicians must take direct responsibility for the patient's life. This can include care-givers or medically trained interpreters who are authorized under the appropriate clinical facility procedures to support patient care. Any inappropriate setting, especially the alarm limit or alarm notification settings, can lead to a hazardous situation that injures the patient, harms the patient, or threatens the patient's life. This equipment should only be operated by trained users who can adjust the settings of the vital signs monitor.

## Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

The subject device (Mediana vital signs monitor, Model V10) is substantially equivalent to the predicate device (current Mediana vital signs monitor, Model V10). They have the same technological characteristics and material, and they are comparable in key safety and effectiveness features and software design and have the same intended uses and basic operation modes as the predicate device.

- The **Non-Invasive Blood Pressure (NIBP)** measurement specifications and performance are equivalent to the predicate device. The subject device is partially modified to display mean arterial pressure (MAP) value. The subject device uses the oscillometric technique to measure non-invasive blood pressure. This measurement technique of blood pressure is not changed and the mean arterial pressure is additionally displayed on LED displays. To verify the accuracy of measuring, the clinical evaluation was performed on adult, pediatric and neonate. The V10 vital signs monitor complies with the testing validations defined in ISO 81060-2 standard so that it is substantially equivalent to predicate devices as Mediana model V10 vital signs monitor.
- The **Pulse rate** specifications and performance derived from either Non-Invasive Blood Pressure (NIBP) or Pulse Oximetry (SpO<sub>2</sub>) are equivalent to the predicate device.
- The **Pulse Oximetry (SpO<sub>2</sub>)** specifications and performance are equivalent to the predicate device.
- The **Temperature** specifications and performance are equivalent to the predicate device.

## Summary of Performance Testing

- **Biocompatibility Testing**

The Mediana vital signs monitor, Model V10 does not contain any patient contact material. See Section 16 “Biocompatibility” of this submission for biocompatibility testing of patient contact accessories.

- **Electrical Safety and Electromagnetic Compatibility Testing**

The Mediana vital signs monitor, Model V10 substantially has been tested in accordance with the IEC 60601-1, IEC 60601-2-49 standards for safety and the IEC 60601-1-2 standard for EMC.

- **Verification and Validation Testing**

The Mediana vital signs monitor, Model V10 substantially has been tested in accordance with the system V & V plan #MDR-EG161022-02 included with the submission.

- **Clinical Testing**

The Mediana vital signs monitor, Model V10 substantially has been tested in accordance with the NIBP and Temp clinical investigations. See Section 20 “Performance testing - Clinical” of this submission.

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Mediana design control procedure. Mediana’s quality system confirms to 21CFR820, ISO13485 and CMDCAS ISO 13485 certified by DNV (Det Norske Veritas).

## Conclusions

As stated above, the V10 is safe and effective, complies with the appropriate medical device guidance and standards and is substantially equivalent to the predicate device.