



August 25, 2016

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

Mediana Co., Ltd
% Mr. Charlie Mack, President
International Regulatory Consultants, LLC
77325 Joyce Way
Echo, Oregon 97826

Re: K152659

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: July 11, 2016
Received: July 25, 2016

Dear Mr. 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.

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)
K152659

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

Mediana Co., Ltd
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Tel) +82-33-742-5400 Fax) +82-33-742-5483

Company Contact: Min-hye, Kim

Date Summary Prepared: July 31th, 2015

Device Name

Trade Name: V10
Common Name: Vital Signs Monitor
Classification Name: NIBP measurement system (21CFR870.1130), also contains non-invasive pulse oximetry, SpO2 (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, Model ARGUS VCM
Cleared by FDA through 510(k) No. **K051375**, and
- **Mediana Co., Ltd.** Pulse Oximeters, Model P10
Cleared by FDA through 510(k) No. **K100225**, and
- **Covidien LLC.** Pulse Oximeters, Model Nellcor Bedside SpO2 Patient Monitoring System, **K142825**, and
- **GE Healthcare.** Vital Signs Monitors, Model CARESCAPE V100
Cleared by FDA through 510(k) No. **K102426**, and
- **Tyco Healthcare Group, LP.** Infrared Tympanic Thermometers, Model Kendall Genius 2
Cleared by FDA through 510(k) No. **K060649**

Device Description

The V10 vital signs monitor is to monitor non-invasive blood pressure, pulse rate, non-invasive functional oxygen saturation of arterial hemoglobin (SpO2) 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 (298 × 218 × 172 (mm) (W×H×D) and 3.4 kg) powered by AC mains (100-240VAC, 50-60Hz) and also powered by internal battery. The monitor provides patient data and monitoring status on 7-segment and 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 (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.

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

The Mediana vital signs monitor, Model V10 is substantially equivalent to Mediana Co., Ltd. vital signs monitors Model ARGUS VCM, Mediana Co., Ltd. Pulse Oximeter Model P10, Covidien LLC. Pulse Oximeter Model Nellcor Bedside SpO₂ Patient Monitoring System, GE Healthcare vital signs monitors Model CARESCAPE V100 and Tyco Healthcare Group, LP. Infrared tympanic thermometers Model Kendall Genius2.

- The **Non-Invasive Blood Pressure (NIBP)** measurement specifications and performance are equivalent to Mediana Co., Ltd. vital signs monitors Model ARGUS VCM. Mediana Co., Ltd. vital signs monitors Model ARGUS VCM complies the same AAMI SP10 standard as Mediana vital signs monitor, Model V10.
- The **Pulse rate** specifications and performance derived from either Non-Invasive Blood Pressure (NIBP) or Pulse Oximetry (SpO₂) are equivalent to Mediana Co., Ltd. vital signs monitors Model ARGUS VCM, Mediana Co., Ltd. Pulse Oximeter Model P10, Covidien LLC. Pulse Oximeter Model Nellcor Bedside SpO₂ Patient Monitoring System.
- The **Pulse Oximetry (SpO₂)** specifications and performance are equivalent to Mediana Co., Ltd. Pulse Oximeter Model P10, Covidien LLC. Pulse Oximeter Model Nellcor Bedside SpO₂ Patient Monitoring System.
- The **Temperature** specifications and performance are equivalent to GE Healthcare vital signs monitors Model CARESCAPE V100 and Tyco Healthcare Group, LP. Infrared tympanic thermometers Model Kendall Genius2.

Summary of Performance Testing

The Mediana vital signs monitor, Model V10 substantially has been tested in accordance with the system V & V plan #MDR-EG140718-01 included with the submission using production equivalent units prior to release to market.

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 conforms 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.