October 9, 2020

Mediana Co., Ltd.
% Charlie Mack
Principal Engineer
International Regulatory Consultants
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K200434
Trade/Device Name: V20, V20a, AVSM3 SNF
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DQA, FLL
Dated: August 30, 2020
Received: September 10, 2020

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. 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,

LT Stephen Browning
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K200434

Device Name
V20, V20a, AVSM3 SNF

Indications for Use *(Describe)*
The V20, V20a, AVSM3 SNF are intended to be used to monitor noninvasive blood pressure (NIBP) - systolic, diastolic and mean arterial pressures, functional arterial oxygen saturation (SpO2), pulse rate (PR) and temperature (TEMP) 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 V20 and V20a are for adult, pediatric and neonatal patients and the AVSM3 SNF is for adult patients only. Also, the V20 is only suitable for single measurement but V20a and AVSM3 SNF are suitable for single as well as continuous measurement.

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 ambulance, 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

Submitter

Mediana Co., Ltd.
132, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Republic of Korea
Tel) +82-33-742-5400 Fax) +82-33-742-5483

Company Contact: Dana Mun

Date Summary Prepared: January 10th 2020

Device Name

Trade Name:	V20, V20a, AVSM3 SNF
Common Name:	Vital Signs Monitor
Classification Name:	NIBP measurement system (21CFR870.1130), also contains Non-invasive pulse oximetry, SpO_2 (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 V20, V20a, AVSM3 SNF are:

- Mediana Co., Ltd. Vital Signs Monitors, V10 and AVSM2
  Cleared by FDA through 510(k) No. **K170497**
- Covidien, Nellcor™ Bedside Respiratory Patient Monitoring System
  Cleared by FDA through 510(k) No. **K141518**
- SunTech Cardiac Monitor, LifeWindow LW8 Lite
  Cleared by FDA through 510(k) No. **K183687**
- Covidien, Filac 3000 Thermometer
  Cleared by FDA through 510(k) No. **K003313**
- Exergen Termometer
  Cleared by FDA through 510(k) No. **K011291**

Device Description

The V20, V20a, AVSM3 SNF are intended to be used to monitor noninvasive blood pressure (NIBP) - systolic, diastolic and mean arterial pressures, functional arterial oxygen saturation (SpO_2), pulse rate (PR) and temperature (TEMP) 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 V20 and V20a are for adult, pediatric and neonatal patients and the AVSM3 SNF is for adult patients only. Also, the V20 is only suitable for single measurement but V20a and AVSM3 SNF are suitable for single as well as continuous measurement.
The Mediana V20, V20a, AVSM3 SNF vital signs monitors are a lightweight and compact device (249 x 211 x 176 (mm) (W×H×D) and 3.1 kg for Standard configuration) powered by AC mains (100-240VAC, 50Hz/60Hz) and also powered by internal battery. The monitor provides patient data and monitoring status on 8" TFT-LCD screen.

Intended Use

The V20, V20a, AVSM3 SNF are intended to be used to monitor noninvasive blood pressure (NIBP) - systolic, diastolic and mean arterial pressures, functional arterial oxygen saturation (SpO_2), pulse rate (PR) and temperature (TEMP) 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 V20 and V20a are for adult, pediatric and neonatal patients and the AVSM3 SNF is for adult patients only. Also, the V20 is only suitable for single measurement but V20a and AVSM3 SNF are suitable for single as well as continuous measurement.

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 V20, V20a, AVSM3 SNF, is substantially equivalent to Mediana vital signs monitor V10, Covidien Nellcor™ Bedside Respiratory Patient Monitoring System, SunTech Cardiac Monitor LifeWindow LW8 Lite, Covidien Filac 3000 Thermometer, Exergen Thermometer.

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 Mediana Co., Ltd. vital signs monitors V10 and SunTech LifeWindow LW8 Lite. The clinical studies which were carried out by SunTech and AND companies were used to support different NIBP modules of the subject device under their original 510(k) submissions, and that Mediana has licensed the two NIBP modules for use in the subject device.
- The **Pulse rate** specifications and performance derived from either Non-Invasive Blood Pressure (NIBP) or Pulse Oximetry (SpO_2) are equivalent to Mediana Co., Ltd. vital signs monitors V10, SunTech LifeWindow LW8 Lite and Covidien Nellcor™ Bedside Respiratory Patient Monitoring System.
- The **Pulse Oximetry (SpO_2)** specifications and performance are equivalent to Mediana V10 vital signs monitor and Covidien Nellcor™ Bedside Respiratory Patient Monitoring System.

- The **Temperature** specifications and performance are equivalent to Covidien Genius 2 thermometer, Covidien Filac 3000 thermometer and Exergen thermometer.

Summary of Performance Testing

The Mediana vital signs monitor, Model V20, V20a, AVSM3 SNF substantially has been tested in accordance with the system V & V plan #MDR-EG160311-01 included with the submission using production equivalent units prior to release to market.

The bench testing (electrical safety testing, EMC testing, IEC60068-2-27, IEC60068-2-64, IEC60068-2-1/2-2/2-30 and ISTA 2A test) has been performed and the results all tests demonstrate that the subject device is substantially equivalent to the predicated device.

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, ISO 13485 certified by BSI.

Conclusions

As stated above, the V20, V20a, AVSM3 SNF all comply with the appropriate medical device guidance and standards and are substantially equivalent to the predicate devices.