October 17, 2017

Rudolf Riester GmbH
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

Re: K170538
Trade/Device Name: RVS-100 Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: September 5, 2017
Received: September 12, 2017

Dear Diana Hong:

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 (DICE) 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 (DICE) 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170538

Device Name
RVS-100 Vital Signs Monitor

Indications for Use *(Describe)*
The RVS-100 vital signs monitor is intended to be used for monitoring, displaying, reviewing, storing and sending alarms regarding multiple physiological patient parameters, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), and Temperature (Temp).
The RVS-100 vital signs monitor is intended to be used in controlled, hospital environments. It is not intended for helicopter transport, hospital ambulance or home use.

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.

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510(k) Summary

This 510(k) Summary of 510(k) information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K170538

1. Date of Submission:8/25/2017

2. Sponsor Identification

Rudolf Riester GmbH
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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name:RVS-100 Vital Signs Monitor
Proposed Device Common Name: Vital Signs Monitor

Regulatory Information:
Classification Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms);
Classification: II;
Product Code: MWI;
Regulation Number: 21 CFR 870.2300;
Review Panel: Cardiovascular;

Intended Use Statement:

The RVS-100 vital signs monitor is intended to be used for monitoring, displaying, reviewing, storing and sending alarms regarding multiple physiological patient parameters, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), and Temperature (Temp).

The RVS-100 vital signs monitor is intended to be used in controlled, hospital environments. It is not intended for helicopter transport, hospital ambulance or home use.

5. Predicate Device Identification

510(k) Number: K153135
Product Name: Vital Signs Monitor V6
Manufacturer: Guangdong Biolight Meditech Co., Ltd

6. Device Description

The Riester RVS-100 vital signs monitor can perform automatic blood pressure, pulse oximetry and body temperature measurements for clinical professionals. The RVS-100 is a portable device, consist of main unit and accessories, including NIBP cuff, Temperature sensor, and SpO_2 sensor.

RVS-100 vital signs monitor has a DC power connector, RVS-100 can connect with extension device RVS-200 and supply power for RVS-200 through the DC power connector.

Note: RVS-200 Wall Diagnostic Station mainly consists of reservoir for ear specula and probe cover. It is classified as a Class I 510(k) Exempt medical device, and not included in this 510(k) submission

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-8: 2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 80601-2-30:2013 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 80601-2-61:2011 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 80601-2-56: 2009 Medical electrical equipment – Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.

8. Clinical Test Conclusion

Non-clinical testing is included in this submission, because all modules have been previously cleared by FDA.

9. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, energy source and fluency, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	**Proposed Device** RVS-100 Vital Signs Monitor	**Predicate Device** Vital Signs Monitor V6	**Remark**
Product Code	MWI	MWI	Same
Regulation No.	870.2300	870.2300	Same
Class	II	II	Same
Intended use	The RVS-100 vital signs monitor is intended to be used for monitoring,	The Vital Signs Monitor V6 is intended to be used for monitoring, displaying,	Similar

	displaying, reviewing, storing and sending alarms regarding multiple physiological patient parameters, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), and Temperature (Temp). The RVS-100 vital signs monitor is intended to be used in controlled, hospital environments. It is not intended for helicopter transport, hospital ambulance or home use.	reviewing, storing and alarming of multiple physiological parameters of patients, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2) and Temperature (Temp). The Vital Signs Monitor V6 is intended to be use in outpatient departments and emergency treatment rooms of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.	
Intended Population	The monitors are intended for adult, pediatric and neonatal.	The monitors are intended for adult, pediatric and neonatal.	Same
Intended Environment	The RVS-100 vital signs monitor is intended to be used in outpatient departments, emergency treatment rooms, and low-acuity areas of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.	The vital signs monitor is used to be used in hospital environments including out-patient outpatient departments, wards and NICU. It is not intended for helicopter transport, hospital ambulance or home use.	Same
Power Supply	The monitors can be supplied by AC power.	The monitors can be supplied by AC power.	Similar
Number of Patient be monitored each time	Single patient each time	Single patient each time	Same
Sterile	No	No	Same

The proposed device, RVS-100 Vital Signs Monitor, is determined to be Substantially Equivalent (SE) to the predicate device.