Taiwan Aulisa Medical Devices Technologies, Inc.
% Don Mizota
Consultant
Don Mizota
725 Morninghome Road
Danville, California 94526

Re: K182822
Trade/Device Name: Guardian Angel Rx GA 1001 Digital Vital Sign Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 28, 2019
Received: February 1, 2019

Dear Don Mizota:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182822

Device Name
Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System

Indications for Use *(Describe)*
The Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is indicated for spot-checking and/or continuous monitoring of pediatrics and infants during non-motion and under well-perfused conditions. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

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.

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Section 5: 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92

5.1. General Information

Date of Preparation: February 1, 2019

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5.2. Trade/Device Name

Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System

5.3. Regulatory Information

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulation Class: Class II

Product Code: DQA

5.4. Predicate

Predicate device

K040589, Avant 9600 Digital Pulse Oximeter, Nonin Medical, Inc.

Reference device

K162580, Guardian Angel GA1000 Digital Vital Sign Monitoring System

5.5. Device Description

The subject device is a digital vital sign monitoring system that measures and displays a patient's pulse rate and oxygen saturation (SpO_2). The subject device consists of a self-contained foot-worn sensor module (SM) and a portable, table-top wireless display unit (DU). It uses non-invasive red and infrared technology to measure the pulse rate and SpO_2. The measurements taken by the SM are wirelessly transmitted to the DU for display using Bluetooth technology. The subject device also provides visual and auditory alarms that alert the caregiver when a patient's pulse rate and/or SpO_2 falls outside of preset limits or when a technical error is detected.

5.6. Intended Use

The Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is indicated for spot-checking and/or continuous monitoring of pediatrics and infants during non-motion and under well-perfused conditions. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.

5.7. Comparison of Indications and Technological Characteristics

The subject device has similar intended use and technology characteristics to the predicate device, K040589, Avant 9600 Digital Pulse Oximeter, except that the subject device is indicated for a narrower range of patient population and environment of use than the predicate, and that the subject device wirelessly transmits data for remote display but the predicate does not.

The subject device uses a similar display unit as our reference device, K162580, Guardian Angel GA1000 Digital Vital Sign Monitoring System, which uses a liquid-crystal display (LCD) for display and Bluetooth technology for data transmission, except that the size of the display panel is enlarged.

The comparison table for the subject device versus the predicate device, K040589, and the reference device, K162580, is shown in ***Table 5.1***.

Table 5.1 – Comparison with Predicate

Item	Subject Device	Predicate Device	Reference Device
	Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System	*Avant 9600 Digital Pulse Oximeter (K040589) with Reusable Flex Sensors*	*Guardian Angel GA1000 Digital Vital Sign Monitoring System (K162580)*
Indication for use	The Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is indicated for spot-checking and/or continuous monitoring of pediatrics and infants during non-motion and under well-perfused conditions. The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.	The Nonin Avant 9600 Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients in hospitals, medical facilities, home care, and subacute environments. It may also be used in patient transport, sleep laboratories, and EMS environments. The Avant 9600 is intended for continuous monitoring and/or spot-checking of patients during both no motion and motion conditions, for patients who are well or poorly perfused.	The Guardian Angel GA1000 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients. It is indicated for spot-checking and / or continuous monitoring of patients during non-motion and under well-perfused conditions. The intended environment of use is hospital. This system is a reusable device.
Patient population	Pediatrics and infants	Adult and pediatric, infant, and neonatal patients	Adults and pediatrics
Application site	Foot	Finger, toe or foot	Finger
Environment of use	Hospitals, medical facilities, home care, and subacute environments	Hospitals, medical facilities, home care, transport and subacute environments	Hospitals
Out-of-hospital transport	No	Yes	No
Motion	Non-motion	Non-motion Motion	Non-motion
Perfusion	Well-perfused	Well-perfused Poorly-perfused	Well-perfused
Single-use or reusable	Reusable	Reusable	Reusable
Measurement	Pulse rate and SpO_2	Pulse rate and SpO_2	Pulse rate and SpO_2

Item	Subject Device		Predicate Device		Reference Device	
	Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System		*Avant 9600 Digital Pulse Oximeter (K040589) with Reusable Flex Sensors*		*Guardian Angel GA1000 Digital Vital Sign Monitoring System (K162580)*	
Technology of pulse oximetry	Red and Infrared technology		Red and Infrared technology		Red and Infrared technology	
LED wavelengths & output power of pulse oximetry	Red: 660 nm @ 9.8 mw Infrared: 880 nm @ 6.5 mw		Red: 660 nm @ 0.8 mw max. avg. Infrared: 910 nm @ 1.2 mw max. avg		Red: 660 nm @ 1.8 mw Infrared: 905 nm @ 2 mw	
Accuracy (No motion)	SpO_2	± 3 digits (70-100%)	SpO_2	± 3 digits (70-100%)	SpO_2	± 3 digits (70-100%)
	Pulse Rate	± 3 digits (30-300 bpm)	Pulse Rate	± 3 digits (18-300 bpm)	Pulse Rate	± 3% (30-290 bpm)
Displayed range	SpO_2	1-100%	SpO_2	0-100%	SpO_2	1-100%
	Pulse Rate	30-300 bpm	Pulse Rate	18-300 bpm	Pulse Rate	30-290 bpm
Display	10.1” LCD		LED		7” LCD	
Alarms	Visual and auditory alarms		Visual and auditory alarms		Visual and auditory alarms	
Power Supply	Sensor Module: Lithium battery Display Unit: Lithium battery, AC adaptor		Monitor: NiMH battery, AC adaptor		Sensor Module: Lithium battery Display Unit: Lithium battery, AC adaptor	
Wireless technology/Data transmission	Bluetooth		None		Bluetooth	
Biocompatibility	Skin (surface) contact Prolonged contact		Skin (surface) contact Prolonged contact		Skin (surface) contact Prolonged contact	

5.8. Summary of Performance Testing

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device. The device complies with the IEC 60601-1, IEC 60601-1-11, IEC 60601-1-8 and ISO 80601-2-61 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Clinical Study

Clinical data were collected, according to Clause 201.12.1.101.2 and Annex EE.2 of ISO 80601-2-61:2011 Standard, to verify the accuracy of the subject device on healthy subjects over the range of 70%-100% SpO2 through controlled induced hypoxia. Over 200 data points were collected. The Arms is below 3%, compliant with FDA guidance on Pulse Oximeters – Premarket notification submissions [510(k)].

5.9. Substantially Equivalent Conclusion

Based on the non-clinical testing and clinical data summarized in this 510(k) submission, the results demonstrate that the subject device is substantially equivalent to the predicate. The differences do not raise different questions of safety or effectiveness when compared to the predicate.