June 25, 2019

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

Re: K191207
Trade/Device Name: Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DRG
Dated: May 23, 2019
Received: May 28, 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/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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191207

Device Name
Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System

Indications for Use *(Describe)*
The Guardian Angel Rx GA2001 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.

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Section 7: 510(k) Summary

K191207

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

7.1 General Information

Date of Preparation: April 30, 2019

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7.2 Trade/Device Name

Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System

7.3 Regulatory Information

Regulation Number	Regulation Name	Regulation Class	Product Code
21 CFR 870.2700	Oximeter	Class II	DQA
21 CFR 870.2910	Radiofrequency Physiological Signal Transmitter and Receiver	Class II	DRG

7.4 Predicate

Predicate device

K182822, Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System, Taiwan Aulisa Medical Devices Technologies, Inc.

Reference device

K183067, Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System, Taiwan Aulisa Medical Devices Technologies, Inc.

7.5 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). It is also equipped with an audio/video camera to monitor the patient in real time. In addition, the subject device 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. During a physiological alarm event, the pulse rate and SpO_2 data along with the audio/video data are recorded automatically by the subject device. The caregiver can review the historical data whenever needed.

The system consists of a self-contained foot-worn Sensor Module, a Receiver/Transponder with an embedded audio/video camera and a portable, table-top wireless Display Unit.

It uses non-invasive red and infrared technology to measure the pulse rate and SpO_2. The measurements are taken by the Sensor Module and are transmitted to the Receiver/Transponder which delivers the measurements along with audio/video signals to the Display Unit for display, wherein Bluetooth technology is used to transmit data between the Sensor Module and the Receiver/Transponder, and data is transmitted from the Receiver/Transponder to the Display Unit via the Wi-Fi 802.11 band.

7.6 Intended Use

The Guardian Angel Rx GA2001 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.

7.7 Comparison of Indications and Technological Characteristics

Fundamental scientific technology and intended use of the subject device are the same as the predicate device, K182822. The subject device was modified to (1) add Wi-Fi capability to extend the data transmission range, and to (2) include a real-time audio/video monitoring feature. The new characteristics added to the subject device are the same as reference device, K183067; and they were verified and validated according to the same procedures cleared under K183067.

A comparison table for the subject device versus the predicate device, K182822, and the reference device, K183067, is shown in ***Table 7.1***.

Table 7.1 – Comparison with Predicate and Reference

Item	**Subject Device**	**Predicate Device**	**Reference Device**
	Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System	*Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System (K182822)*	*The Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System (K183067)*
Indication for use	The Guardian Angel Rx GA2001 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 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 Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and audio video signals 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 environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device.
Patient population	Pediatrics and infants	Pediatrics and infants	Adult and pediatric
Application site	Foot	Foot	Finger
Environment of use	Hospitals, medical facilities, home care, and subacute environments	Hospitals, medical facilities, home care, and subacute environments	Hospitals, medical facilities, home care, and subacute environments
Out-of-hospital transport	No	No	No
Motion	Non-motion	Non-motion	Non-motion

Item	Subject Device		Predicate Device		Reference Device	
	Guardian Angel Rx GA2001 Digital Vital Sign Monitoring System		*Guardian Angel Rx GA1001 Digital Vital Sign Monitoring System (K182822)*		*The Guardian Angel Rx GA2000 Digital Vital Sign Monitoring System (K183067)*	
Perfusion	Well-perfused		Well-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	
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 @ 9.8 mw Infrared: 880 nm @ 6.5 mw		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 (18-300 bpm)	Pulse Rate	± 3 digits (18-300 bpm)	Pulse Rate	± 3% (30-290 bpm)
Displayed range	SpO_2	0-100%	SpO_2	0-100%	SpO_2	1-100%
	Pulse Rate	18-300 bpm	Pulse Rate	18-300 bpm	Pulse Rate	30-290 bpm
Display	10.1” LCD		10.1” LCD		10.1” LCD	
Alarms	Visual and auditory alarms		Visual and auditory alarms		Visual and auditory alarms	
Power Supply	Lithium battery, AC adaptor		Lithium battery, AC adaptor		Lithium battery, AC adaptor	
Real-time audio/video	Yes		No		Yes	
Wireless technology/Data transmission	Bluetooth 802.11		Bluetooth		Bluetooth 802.11	
Biocompatibility	Skin (surface) contact Prolonged contact		Skin (surface) contact Prolonged contact		Skin (surface) contact Prolonged contact	

7.8 Summary of Performance Testing

The performance data are summarized below 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)].

7.9 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.