DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 3, 2017

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

Re: K162580
Trade/Device Name: Guardian Angel GA1000 Digital Vital Sign Monitoring System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 26, 2017
Received: January 30, 2017

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. 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,

Lori A. Wiggins -S

for
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162580

Device Name

Guardian Angel GA1000 Digital Vital Sign Monitoring System

Indications for Use *(Describe)*

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.

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 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 Summary Prepared: September 13th, 2016

Submitted by: Taiwan Aulisa Medical Devices Technologies, Inc.
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5.2. Name of Device

Trade Name:	Guardian Angel GA1000 Digital Vital Sign Monitoring System
Common Name:	Pulse Oximeter
Classification:	Oximeter CFR §870.2700
Class:	Class II
Product Code:	DQA

5.3. Legally Marketed Predicate Devices for Claimed Equivalence

K052669, Avant Digital Pulse Oximetry System, Model 4000, 4100, Nonin Medical, Inc.

5.4. Device Description

Aulisa's GA1000 is a digital vital sign monitoring system that measures and displays a patient's pulse rate and oxygen saturation level. The system includes a self-contained wrist-worn Sensor Module and a portable, table-top wireless Display Unit. The Guardian Angel GA1000 Digital Vital Sign Monitoring System is also equipped with an alarm system that alerts the caregiver when a patient's pulse rate is too low or too high and when the patient's SpO_2 is too low or too high.

Guardian Angel GA1000 Digital Vital Sign Monitoring System contains the following components.

- Sensor Module
- Display Unit
- Finger Sensor
- Sensor Module wristband
- Sensor Module Charging Adaptor
- Display Unit Charging Adaptor
- Display Unit Stand

The GA1000 measures SpO_2 and pulse rate based on transmittance technology, measuring the absorbance of red and infrared light passed through the tissue.

The GA1000 uses Bluetooth v4.0 to transmit data between the wrist-worn Sensor Module and the wireless Display Unit. Both the Sensor Module and the Display Unit is Bluetooth® 4.0 compatible.

The GA1000 uses non-invasive red and infrared LED sensors to measure the functional blood oxygen saturation and pulse rate. The measurements are wirelessly transmitted to the Display Unit, which displays the measurements using a Liquid-Crystal-Display (LCD) panel. The system provides adjustable visual and audio oxygen saturation, and pulse rate alarms through the LCD panel and speakers. Additional alarms are featured, including low battery on the Sensor Module, Sensor Cable disconnection, Sensor Module disconnection, Sensor Cable Probe fault, Sensor Probe detached from patient, Display Unit battery low.

5.5. Intended Use

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.

5.6. Technological Characteristics

The comparison table of technological characteristics for Guardian Angel GA1000 Digital Vital Sign Monitoring System and Nonin Avant Digital Pulse Oximetry System is shown as follows:

Table 5.1 – Comparison Table to Predicate Device

	Subject Device		Predicate Device	
Product code	DQA		DQA	
Classification	Class II		Class II	
Principles of Operation	Red and Infra-red transmittance technology		Red and Infra-red transmittance technology	
System Components	Sensor Module and Display Unit		Patient Module and Display Unit	
Wireless technology/ Data Transmission	Bluetooth v4.0		Bluetooth 1.1	
Software level of concern	Medium		Medium	
SpO_2 Specifications (No Motion)	Displayed Range:	1-100%	Displayed Range:	0-100%
	Declared Range:	70-100%	Declared Range:	70-100%
	Accuracy: (Pediatrics : SC100M, ENSC100M; Adults: SC100L, ENSC100L)	Adults/ Pediatrics: 3 digits	Accuracy: (Finger Clip Flexi, Flexifoam, 8000R, 8000Q)	Adults/ Pediatrics: 2 digits 3 digits 4 digits
Pulse Rate Specifications (No motion)	Range:	30-290 bpm	Range:	18-300 bpm
	Accuracy: (SC100M, SC100L, ENSC100M, ENSC100L)	Adults/ Pediatrics: ±3 %	Accuracy: (Finger Clip Flexi, Flexifoam, 8000R, 8000Q)	Adults/ Pediatrics: ±3%

Measurement Wavelengths and Output Power	Red 660 nm @ 1.8 mw nominal Infrared 905 nm @ 2 mw nominal	Red 660 nm @ 3 mw nominal Infrared 910 nm @ 3 mw nominal
System Components	Sensor Module and Display Unit	Patient Module and Display Unit
Power Supply	Sensor Module: 3.7V Lithium battery Display Unit: Lithium battery, AC adaptor	Patient Module: AA battery Display Unit: NiMH battery, AC adaptor
Sensor Form	Soft Finger Sensor	Clip and Wrap Sensor
Alarms	Audible and visual pulse rate and oxygen saturation alarms. Low battery and critical battery, disconnection alarms.	Audible and visual pulse rate, oxygen saturation, and perfusion alarms. Low battery and disconnection alarms.
Indications For Use	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.	The NONIN® Avant® 4000 Digital Pulse Oximetry System is indicated for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, and infant patients. It is indicated for spot checking and/or continuous monitoring of patients during both motion and no motion conditions, and for patients who are well or poorly perfused.

5.7. Substantial Equivalence

The Guardian Angel GA1000 Digital Vital Sign Monitoring System uses technology which is equivalent to the legally marketed predicate device cleared under K052669. The subject device is indicated for monitoring adults and pediatric patients whereas the predicate is indicated for use for monitoring adults, pediatric, and infant patients. In addition, the subject

device is indicated to monitor during non-motion conditions and in poorly perfused patients. These differences are not critical to the intended diagnostic use of the device. The indications of the subject device encompass a smaller patient population and less conditions of use; thus, the differences do not affect the safety and effectiveness of the device when used as labeled.

5.8. Summary of Performance Testing

Accuracy of pulse oximeter, electrical, mechanical, electromagnetic compatibility, software and biocompatibility testing have been performed on the GA1000.

The results of the testing demonstrate that the Taiwan Aulisa Medical Technologies Guardian Angel GA1000 Digital Vital Sign Monitoring System is as safe and effective, as the legally marketed predicate device.

5.8.1. Non-clinical Testing

The following non-clinical testing has been conducted for the GA1000 Digital Vital Sign Monitoring System, performed according to GA1000 product requirement specification and quality system to illustrate substantial equivalence.

Table 5.2 – Utilization of Standards table

Performance Testing	ISO 80601-2-61:2011
Electrical Safety testing	IEC 60601-1:2005
Biocompatibility Testing	ISO 10993-10: 2010, ISO 10993-5:2009
Electrical Safety Testing and EMC Testing	IEC 60601-1-2:2007
Alarm System	IEC 60601-1-8:2006
Wireless Coexistence	FDA Guidance Radio Frequency Wireless Technology in Medical Devices (2013)
Software Verification	IEC 62304:2006 FDA Guidance Off-The-Shelf Software Use in Medical Devices (1999)
Pulse Oximetry Testing	ISO 80601-2-61:2011 FDA Pulse Oximeters Guidance (2013)

The tests performed on the GA1000 include:

- Functional Test

- Push, Impact and Drop Test
- Particulate and Water Ingress Test
- Temperature and Humidity Test
- Battery Life Test
- Radio Frequency Compatibility
- Emissions and Immunity Tests
- Biocompatibility Test
- Alarm System Test

The subject device underwent bench tests following standards listed above. Software Validation and Verification was also performed following IEC 62304:2006. Biocompatibilities of patient contact materials have been tested, showing the materials to be biocompatible. The tests show compliance to IEC 60601-1, IEC 60601-1-2, IEC 60601-8, IEC 62304, ISO 10993-5, ISO 10993-10, and ISO 80601-2-61.

5.8.2. Clinical Testing

Clinical data were collected to verify the performance accuracy of GA1000 on healthy adult subjects over the range of 70%-100% SpO_2 through controlled induced hypoxia. The data was performed according to Clause 201.12.1.101.2 and Annex EE.2 of ISO 80601-2-61:2011 Standard.

Over 200 data points were collected for each sensor. The A_{rms} of each sensor is below 3%, compliant with FDA guidance on Pulse Oximeter – Premarket notification submissions [510(k)]: Guidance for Industry and Food and Drug Administration staff, Issued March 4th, 2013.

5.9. Conclusion

Based on the clinical data and non-clinical testing summarized in 510(k) submission, the result demonstrates Guardian Angel GA1000 Digital Vital Sign Monitoring System is in compliance with design specifications, applicable standards, and the intended use. Performance test data demonstrate substantial equivalence to the predicate device.