February 25, 2025

Taiwan Aulisa Medical Devices Technologies, Inc.
Derow Ma
Assistant Vice President
6F-2, No. 3-1, YuanQu St., Nangang Dist.
Taipei City, 115603
Taiwan

Re: K233963
Trade/Device Name: Aulisa Oximeter Module (2nd Gen.) (GA-OM0007, GA-OM0008)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 5, 2024
Received: July 5, 2024

Dear Derow Ma:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233963

Device Name

Aulisa Oximeter Module (2nd Gen.) (GA-OM0007, GA-OM0008)

Indications for Use *(Describe)*

The Aulisa Oximeter Module (2nd Gen.) is indicated for spot-checking and/or continuous monitoring SpO2 and pulse rate of adult and pediatric patients during non-motion and under well-perfused conditions in hospitals, medical facilities, home care, and subacute environments. The parameters derived by the Aulisa Oximeter Module (2nd Gen.) are transmitted to a commercially available mobile device that runs an Aulisa-developed application for display and review.

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	December 15, 2023
Company Identification	Taiwan Aulisa Medical Devices Technologies, Inc. 6F-2, No. 3-1, YuanQu St., Nangang Dist., Taipei City 115 TW TEL.: +886-2-2655-7297 FAX: +886-2-2655-7260
Contact Person	Show Hsiao Regulatory Affairs Assistant Manager Taiwan Aulisa Medical Devices Technologies, Inc. Email: show.hsiao@aulisa.com

5.2 Trade/Device Name

Aulisa Oximeter Module (2nd Gen.)

5.3 Regulatory Information

Regulation Number	Product Code	Classification Name	Device Class
870.2700	DQA	Oximeter	Class II

5.4 Predicate Device

Primary Predicate
K162580, Guardian Angel Rx GA1000 Series Digital Vital Sign Monitoring System, Taiwan Aulisa Medical Devices Technologies, Inc.

Secondary Predicate
K203208, Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System, Taiwan Aulisa Medical Devices Technologies, Inc.

5.5 Device Description

The Aulisa Oximeter Module (2nd Gen.) is a wireless, wrist-worn Sensor Module (SM) specifically designed to continuously measure and display a patient's pulse rate and oxygen saturation (SpO_2). It uses non-invasive red and infrared technology to measure the vital signs and sends the data to an Aulisa-developed software application as cleared through previous Premarket Notification 510(k) submissions under Guardian Angel Rx GA1000 Series Digital Vital Sign Monitoring System (K162580) & Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (K203208) using Bluetooth technology. If the physiological data sent from the subject device to the software application falls outside of pre-set limits or when a technical error is detected, both auditory and visual alarm signals are generated through the software application while the subject device backlight of the vital sign will turn to RED colour as a visual alarm signal, to alert the caregiver.

The sensor module uses Bluetooth technology to interact with a commercial, third-party mobile device whether under iOS or Android operating system, such as iPad, iPhone, Google Pixel… etc. which is not part of this submission. The vital-signs are transmitted to mentioned mobile device that runs Aulisa-developed application for displayed and reviewed. The software application can be download from an official APP store, such as iOS APP store or Google Play.
The subject device contains an Oximeter Box and two Oximeter Sensor Cables resulting in device configurations and model names as listed below.

Oximeter Module	Oximeter Box	Oximeter Sensor	Population	Parameters
Aulisa Oximeter Module (2nd Gen.) (GA-OM0007)	Oximeter Box (GA-OB0003)	Adult Reusable Oximeter Sensor Cable (GA-RS0005)	Adult	• SpO2 • Pulse Rate
Aulisa Oximeter Module (2nd Gen.) (GA-OM0008)	Oximeter Box (GA-OB0003)	Pediatric Reusable Oximeter Sensor Cable (GA-RS0006)	Pediatric	• SpO2 • Pulse Rate

5.6 Indications for Use

The Aulisa Oximeter Module (2nd Gen.) is indicated for spot-checking and/or continuous monitoring SpO2 and pulse rate of adult and pediatric patients during non-motion and under well-perfused conditions in hospitals, medical facilities, home care, and subacute environments. The parameters derived by the Aulisa Oximeter Module (2nd Gen.) are transmitted to a commercially available mobile device that runs an Aulisa-developed application for display and review.

5.7 Comparison with Predicate Device

The subject device has the same indications for use for measuring SpO2 and pulse rate as the predicate devices (K162580 & K203208) with the exception that the primary predicate device is indicated for use only in hospital while both subject device and secondary predicate device are indicated for use in hospitals, medical facilities, home care, and subacute environments and all three devices are for Rx use only. All three devices use wireless technology to transmit physiological data to a remote display through the software application.

Further, all three devices are wearable biosensors that adhere to the fingertip while both subject device and primary predicate device are indicated for reuse only, but the secondary predicate device can be reusable/ disposable depends on the types of sensor cable.

These differences do not affect the safety and effectiveness of the device when used as labelled. Table 5.7.1 lists the similarities and differences between the subject device and the predicate devices (K162580 & K203208) for more in detail.

Table 5.7.1

	Subject Device	Primary Predicate Device	Secondary Predicate Device	SE determination
Device name	Aulisa Oximeter Module (2nd Gen.)	Guardian Angel GA1000 Digital Vital Sign Monitoring System	Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System	-
Model number	GA-OM0007, GA-OM0008	GA1000	GA2000	-
K number	-	K162580	K203208	-
Manufacturer	Taiwan Aulisa Medical Devices Technologies, Inc.	Taiwan Aulisa Medical Devices Technologies, Inc.	Taiwan Aulisa Medical Devices Technologies, Inc.	Identical
Regulation Number	870.2700	870.2700	870.2700	Identical
Product Code	DQA	DQA	DQA	Identical
Classification	II	II	II	Identical
Indications for use	The Aulisa Oximeter Module (2nd Gen.) is indicated for spot-checking and/or continuous monitoring SpO2 and pulse rate of adult and pediatric patients during non-motion and under well-perfused conditions in hospitals, medical facilities, home care, and subacute environments. The parameters derived by the Aulisa Oximeter Module (2nd Gen.) are transmitted to a commercially available mobile device that runs an Aulisa-developed	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 Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2000) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The intended environments of use are hospitals, medical facilities, home care, and subacute environments. This system is a reusable device. The Oximeter Module(s) is indicated for spot-checking and/or continuous monitoring of SpO2 and PR of adults and pediatrics during non-motion and under well-perfused conditions.	Similar, The primary predicate device is indicated for use only in hospital while both subject device and secondary predicate device are indicated for use in hospitals, medical facilities, home care, and subacute environments

	Subject Device	Primary Predicate Device	Secondary Predicate Device	SE determination
	application for display and review.			
Patient population	adult, pediatric	adult, pediatric	adult, pediatric	Identical
Use environment	hospitals, medical facilities, home care, subacute environments	hospital	hospitals, medical facilities, home care, subacute environments	Similar, The primary predicate device is indicated for use only in hospital while both subject device and secondary predicate device are indicated for use in hospitals, medical facilities, home care, and subacute environments
Measurement	Pulse rate, SpO_2	Pulse rate, SpO_2	Pulse rate, SpO_2	Identical
Disposable or reusable	reusable	reusable	reusable/ disposable	Similar, Both subject device and primary predicate device are indicated for reuse only, while the secondary predicate device can be reusable/ disposable depends on the types of sensor cable
Wireless communication	Bluetooth	Bluetooth	Bluetooth Wi-Fi	Similar, Both subject device and primary predicate device use Bluetooth technology for wireless communication, while the secondary predicate device uses both Bluetooth & Wi-Fi

	Subject Device	Primary Predicate Device	Secondary Predicate Device	SE determination
				technology for wireless communication
Measuring site	Finger	Finger	Finger	Identical
Out-of-hospital transport	No	No	No	Identical
Motion	Non-motion	Non-motion	Non-motion	Identical
Perfusion	Well-perfused	Well-perfused	Well-perfused	Identical
Technology	Red and Infrared technology	Red and Infrared technology	Red and Infrared technology	Identical
Wavelengths & output power	Red: 660 nm	Red: 660 nm @ 1.8 mw	Red: 660 nm @ 1.8 mw	Identical
	Infrared: 905 nm	Infrared: 905 nm @ 2 mw	Infrared: 905 nm @ 2 mw	Identical
Measurement accuracy (No motion)	SpO_2: ± 3 digits (70-100%)	SpO_2: 3 digits	SpO_2: ± 3 digits (70-100%)	Identical
	PR: ± 3 digits (30-290 bpm)	PR: ± 3% (30-290 bpm)	PR: ± 3% (30-290 bpm)	Identical
Displayed range	SpO_2: 1-100% PR: 30-290 bpm	SpO_2: 1-100% PR: 30-290 bpm	SpO_2: 1-100% PR: 30-290 bpm	Identical
Power supply	Lithium battery AC adaptor (Type C)	Lithium battery AC adaptor	Lithium battery AC adaptor	Similar, Both predicate devices use a charging case for connecting to a charging adaptor, while the subject device connect to a charging adaptor directly through a Type C connector. Various testing has been conducted and results indicate that does not affect the safety and effectiveness of the device

	Subject Device	Primary Predicate Device	Secondary Predicate Device	SE determination
Biocompatibility	Skin (surface) contact Prolonged contact	Patient contact	Skin (surface) contact Prolonged contact	Identical

5.8 Summary of Performance Testing

The results of the non-clinical testing demonstrate compliance to applicable standards. Below table summarizes test results for the subject device, which met the relevant requirements of the applicable recognized standards or claimed specifications.

Item	Reference	Result
Electrical Safety	IEC 60601-1 IEC 60601-1-11	Pass
Temperature and Humidity	IEC 60601-1 IEC 60601-1-11	Pass
Atmospheric Pressure (Altitude)	IEC 60601-1	Pass
Electromagnetic Immunity and Emissions	IEC 60601-1-2	Pass
Performance	ISO 80601-2-61	Pass
Mechanical Durability	IEC 60601-1 IEC 60601-1-11	Pass
Biocompatibility: • *In Vitro* Cytotoxicity • Skin Sensitization • Skin Irritation	ISO 10993-5 ISO 10993-10 ISO 10993-23	Pass
Software V&V	FDA Guidance *Guidance for the Content of Premarket Submissions for Device Software Functions*	Pass
Security Testing	FDA Guidance *Cybersecurity in Medical Devices, Quality System Considerations and Content of Premarket Submissions*	Pass
Wireless Coexistence Testing	ANSI C63.27	Pass
Clinical testing	FDA Guidance *Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff*	Pass
Usability testing	FDA Guidance *Applying Human Factors and Usability Engineering to Medical Devices*	Pass
Bench testing	Manufacturer's specifications	Pass
Durability and Performance testing	Manufacturer's specifications	Pass
Battery Life Testing	Manufacturer's specifications	Pass

5.9 Summary of Clinical Testing

The functional oxygen saturation (SpO_2) measurements of the subject device were validated in accordance with ISO 80601-2-61. The clinical evaluation for SpO_2 accuracy was conducted on healthy male and female, light to dark skinned subjects. The SpO_2 accuracy data were calculated using the Accuracy root-mean-square (A_{RMS}) and the results which indicated that the subject device had an A_{RMS} less than 3 digits during steady-state conditions over the range of 70-100% were in compliance with the specified performance claimed by the manufacturer.

5.10 Conclusion

Based on the testing summarized in the 510(k) submission, the results demonstrate that the subject device is substantially equivalent to the predicate device. The differences do not raise any questions of safety or effectiveness when compared to its predicate device.