September 27, 2024

Taiwan Aulisa Medical Devices Technologies, Inc.
Jou An Hsu
Regulatory Affairs Specialist
6F-2, No. 3-1, YuanQu St., Nangang Dist.,
Taipei City, NA 115
Taiwan

Re: K240220
Trade/Device Name: Aulisa Temperature Module (TM0002)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 28, 2024
Received: August 28, 2024

Dear Jou An Hsu:

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,

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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.

510(k) Number *(if known)*
K240220

Device Name
Aulisa Temperature Module (TM0002)

Indications for Use *(Describe)*
Aulisa Temperature Module (TM0002) is a battery-operated electronic device with indication for use in continuously measuring and monitoring armpit body temperature of adults, pediatrics, and infants and transmission of the measuring result via wireless signal.
Aulisa Temperature Module (TM0002) is a non-invasive and reusable device for single patient use with intended environments of use are hospitals, medical facilities, home care, and subacute environments.
The parameters derived by the Aulisa Temperature Module (TM0002) 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.

K240220 - 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	September 27, 2024
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	Ann Hsu Regulatory Affairs Specialist Taiwan Aulisa Medical Devices Technologies, Inc. Email: ann.hsu@aulisa.com

5.2 Trade/Device Name

Aulisa Temperature Module (TM0002)

5.3 Regulatory Information

Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Common Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL

5.4 Predicate Device(s)

Predicate Device

- K181013, Fever Scout™ Continuous Monitoring Thermometer, VivaLnk Inc.

Reference Device

- K203208, Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (specifically model GA2002), Taiwan Aulisa Medical Devices Technologies, Inc.

5.5 Device Description

The Aulisa Temperature Module (TM0002) is indicated for continuous armpit body temperature monitoring of adults, pediatrics, and infants which measures body temperature and sends the physiological data to an Aulisa-developed software application as cleared through previous Premarket Notification 510(k) submissions under 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 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 display and review. The software application can be downloaded from an official APP store, such as iOS APP store or Google Play.

The Subject Device is reusable, and its intended environments of use are hospitals, medical facilities, home care, and subacute environments.

The device model, device name, population and parameters of the Subject Device are described below:

Device Model	Aulisa Sensor Module(s)	Population	Parameters
TM0002	Aulisa Temperature Module	• Adult • Pediatric • Infant	Body Temperature

5.6 Indications for use

Aulisa Temperature Module (TM0002) is a battery-operated electronic device with indication for use in continuously measuring and monitoring armpit body temperature of adults, pediatrics, and infants and transmission of the measuring result via wireless signal. Aulisa Temperature Module (TM0002) is a non-invasive and reusable device for single patient use with intended environments of use are hospitals, medical facilities, home care, and subacute environments.
The parameters derived by the Aulisa Temperature Module (TM0002) 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 similar intended use and technological characteristics to the Predicate device, Fever Scout™ Continuous Monitoring Thermometer (K181013), except that the Predicate device is powered by Rechargeable Lithium Battery, but the Subject Device is powered by non-Rechargeable Coin Battery.

The Subject Device is used together with pre-installed Aulisa-developed software application which has been cleared through previous Premarket Notification 510(k) submission under Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (K203208), thereafter referred to as the Reference device in this submission.

These differences do not affect the safety and effectiveness of the device when used as labeled. Table 5.7.1 and 5.7.2 list the similarities and differences between the Subject Device and Predicate device (K181013), along with Reference device (K203208, specifically model GA2002).

Table 5.7.1 Comparison Table to Predicate

	Subject Device	Predicate	Comparison
Device name	Aulisa Temperature Module (TM0002)	Fever Scout™ Continuous Monitoring Thermometer	--
K number	-	K181013	--
Product code	FLL	FLL	**Identical**
Regulation Number	21 CFR 880.2910	21 CFR 880.2910	**Identical**
Regulation description	Clinical Electronic Thermometer	Clinical Electronic Thermometer	**Identical**
Classification	II	II	**Identical**
Indications for use	Aulisa Temperature Module (TM0002) is a battery-operated electronic device with indication for use in continuously measuring and monitoring armpit body temperature of adults, pediatrics, and infants and transmission of the measuring result via wireless signal. Aulisa Temperature Module (TM0002) is a non-invasive and reusable device for single patient use with intended environments of use are hospitals, medical facilities, home care, and subacute environments. The parameters derived by the Aulisa Temperature Module (TM0002) are transmitted to a	The wireless Fever Scout™ Continuous Monitoring thermometer is a non-invasive and re-usable electronic device for home use and a non-invasive and single patient use in the hospital. This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.	**Different** Note 1

	commercially available mobile device that runs an Aulisa-developed application for display and review.		

	Subject Device	Predicate	Comparison
Patient population	adult, pediatric, infant	ages 29 days and older	**Different** Note 2
Use environment	hospitals, medical facilities, home care, subacute environments	home, hospital	**Different** Note 3
Dimension	24mm x 32.8mm x 5.5mm	61mm x 41mm x 5.5mm	**Different** Note 4
Measurement	body temperature	body temperature	**Identical**
Disposable or reusable	Reusable (Temperature Module) disposable (Patch)	reusable/ disposable	**Identical**
Wireless communication	Bluetooth 5.2	Bluetooth BLE Wireless (Wi-Fi) 2.4G	**Different** Note 5
Operating platform	Mobile device with pre-installed Aulisa-developed application • iOS 13.0 or later • Android 6.0 or later	• iPhone 5S+ or later & iOS 8.0 or later • Android 4.3 or later	**Identical** Both devices operate on a platform with compatible application and indicate a software operating system has been used instead of a hardware.

	Subject Device	Predicate	Comparison
Alarm	Visual and auditory alarms	NA	**Different** Note 6
Measurement accuracy	Under 37℃: ±0.2℃ 37.1~39.0℃: ±0.1℃ 39℃ and above: ±0.2℃	98.6°F-102.2°F: ±0.2°F (37°C-39°C: ±0.1°C) 95°F-98.6°F: ±0.4°F **(**35°C- 37°C: ±0.2°C**)** 102.2°F-107.6°F: ±0.4°F (39°C-42°C: ±0.2°C)	**Different** Note 7
Display range	89.6°F-107.6°F (32°C-42°C) <89.6°F (32.0°C) displays “Lo” >107.6°F (42.0°C) displays “Hi”	95°F- 107.6°F (35°C- 42°C)	**Different** Note 8
Operation mode	Continuous	Continuous	**Identical**
Measuring site	Axillary (armpit)	Axillary (armpit)	**Identical**

	Subject Device	Predicate	Comparison
Power supply	CR1216	MS Lithium rechargeable battery 3.0V	**Different** Note 9

Note 1
Both devices function as a thermometer which have the same indication for use for body temperature monitoring, except that the patient population of Subject Device is “adults, pediatrics, and infants” while Predicate Device is “from ages 29 days and older”. Clinical accuracy testing was conducted to ISO 80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Note 2
The patient population of subject device is “adults, pediatrics, and infants” while the predicate device is “from ages 29 days and older”. Clinical accuracy testing was conducted to ISO 80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Note 3
The use environment of subject device is “hospitals, medical facilities, home care, subacute environments” whereas the predicate device is limited to “home, and hospital” only. The Subject Device has undergone testing per IEC 60601-1:2005 + A1:2012 + A2:2020, FCC Part 15 Subpart C§ 15.249. Additionally, performance data comprising software verification, cybersecurity analysis, wireless coexistence testing, and usability testing demonstrate that this difference does not raise different questions of safety and effectiveness.

Note 4
The dimension of Subject Device is smaller than the Predicate Device. However, the difference does not raise different questions of safety and effectiveness.

Note 5
Both devices transmit the measuring result via wireless signal, except that Subject Device sends out data through Bluetooth only while Predicate sends out data through both Bluetooth and Wi-fi. The Subject Device has undergone testing per IEC 60601-1:2005 + A1:2012 + A2:2020, FCC Part 15 Subpart C§ 15.249. Additionally, performance data comprising software verification, cybersecurity analysis, wireless coexistence testing, and usability testing demonstrate that this difference does not raise different questions of safety and effectiveness.

Note 6
The predicate device does not have an alarm system, whereas the subject device includes "Visual and auditory alarms" integrated with a pre-installed application that is identical to that of the reference device. This difference does not raise new questions of safety or effectiveness, as the alarm system has been previously validated in the reference device.

Note 7
Both devices have the same "Measurement accuracy between 37.1°C-39°C with ±0.1°C".
The subject device has Measurement accuracy under 37°C or above 39°C with ±0.2°C, while the predicate device has Measurement accuracy between 35°C-37°C and 39°C-42°C with ±0.2°C. Clinical accuracy testing was conducted per ISO 80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Note 8
The subject device has the Display range between 32°C-42°C and have "Hi, Lo" display while out of range. The predicate device has the same Display range between 35°C-42°C but does not have "Hi, Lo" display while out of range. Performance testing was conducted to ISO 80601-2-56. Therefore, the difference does not raise different questions of safety and effectiveness.

Note 9
Both devices are battery powered, while the only difference being that the subject device uses a Coin Battery, while the predicate uses a Rechargeable Lithium Battery. The subject device underwent testing in accordance with IEC 60601-1:2005 + A1:2012 + A2:2020, and the results demonstrated compliance with safety requirements. Therefore, this difference does not impact the safety and effectiveness of the device.

5.8 Summary of Non-clinical Testing

The results of the testing demonstrate equivalence with the predicate device(s) and compliance with recognized standards. The table below 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 80601-2-56 ASTM E1112	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	Pass
Wireless Coexistence Testing	ANSI C63.27	Pass
FDA Guidance		
Software V&V	*Guidance for the Content of Premarket Submissions for Device Software Functions*	Pass
Security Testing	*Cybersecurity in Medical Devices, Quality System Considerations and Content of Premarket Submissions*	Pass
Usability testing	*Applying Human Factors and Usability Engineering to Medical Devices*	Pass
Clinical electronic thermometer	*Enforcement Policy for Clinical Electronic Thermometers* *Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers*	Pass
Manufacturer's specifications		
Bench testing	Durability and Performance testing Battery Life Testing	Pass

5.9 Summary of Clinical Testing

The accuracy of the Subject Device was validated in accordance with ISO 80601-2-56 and ASTM E1112. The output temperature of the Subject Device is derived directly from input signal without any adjustment, and therefore no clinical validation is needed.

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 devices. The differences do not raise any new questions of safety or effectiveness when compared to its predicate devices.