October 30, 2020

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

Re: K202497
Trade/Device Name: Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, MWI
Dated: August 25, 2020
Received: August 31, 2020

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,

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics, & Monitoring Devices
Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202497

Device Name
Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000

Indications for Use *(Describe)*
The Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000, is intended to provide remote central monitoring and display of information as recorded by multiple Aulisa single-patient monitoring systems, on a central remote screen. The system can be used in a hospital type and clinic environment.

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: August 25, 2020

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

Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000

5.3. Regulatory Information

Regulation Number	Regulation Name	Regulation Class	Product Code
21 CFR 870.2300	System, Network and Communication, Physiological Monitors	Class II	MSX
21 CFR 870.2300	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)	Class II	MWI

5.4. Predicate Device

Predicate

K151006, EarlySense Central Display Station, EarlySense Ltd.

5.5. Device Description

The Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000, operates through an Aulisa-developed software installed on a standard personal computer. The system interlinks multiple Aulisa single-patient monitoring systems to display the information as recorded by each single-patient monitoring system on a central remote screen. The system uses standard off-the-shelf communication and IT hardware for data transmission.

The information transmitted from single-patient monitoring systems to the MP1000 system includes the physiological parameters and alarm indications. Adjusting alarm settings can only be performed on the Aulisa Display Unit of the single-patient monitoring system. If configured, the MP1000 screen can also be accessed through remote devices, such as other PCs. In addition, patient history data and report files can be viewed, exported, and/or printed.

5.6. Intended Use

The Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000, is intended to provide remote central monitoring and display of information as recorded by multiple Aulisa single-patient monitoring systems, on a central remote screen. The system can be used in a hospital type and clinic environment.

5.7. Comparison with Predicate

The subject device has similar intended use and technology characteristics to the predicate device, which is to provide remote central monitoring through the display of physiological parameters as recorded by individual monitoring units on a central remote screen. The physiological parameters displayed on the subject device are similar to the parameters displayed by the predicate device, EarlySense Central Display Station. Both devices classify as stand-alone software and run on an off-the-shelf computer, with the subject device operating on a Windows 10 operating system and the predicate device on a Linux operating system. The communication method used on both devices for data transmission is either via standard wired or via wireless LAN. The subject device provides the accessibility to remotely view the central remote screen from additional PCs, like its predicate device.

Additionally, the MP1000 and its predicate device are used in the same clinical environments-hospitals or hospital type and clinic environment.

Further, audio/visual alarm notification is provided for both subject and predicate devices. Both devices do not perform analysis of data, but only duplicate the data received from the individual monitoring units. The subject device does not allow for the adjustment of the monitoring unit's settable parameters from the remote station, whereas the predicate device does. These differences do not affect the safety and effectiveness of the device when used as labeled.

The comparison table for the subject device versus the predicate device, EarlySense Central Display Station (K151006) is shown in ***Table 5.1***.

Table 5.1 – Comparison with Predicate

Item	Subject Device	Predicate Device
	Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000	*EarlySense Central Display Station, (K151006)*
Indication for use	The Aulisa Multiple Patient Digital Vital Sign Monitoring System, MP1000, is intended to provide remote central monitoring and display of information as recorded by multiple Aulisa single-patient monitoring systems, on a central remote screen. The system can be used in a hospital type and clinic environment.	The EarlySense Central Display System is intended to provide remote central monitoring and display of information as recorded by multiple EarlySense bedside units, on a central remote screen. The system can be used in hospitals or hospital type and clinic environment.
Environment of use	Hospitals or hospital type and clinic environment	Hospitals or hospital type and clinic environment
Alarms	Visual and auditory alarms	Visual and auditory alarms
Operating System	Windows 10	Linux Debian
Communication Method	LAN and wireless LAN	LAN and wireless LAN
Alarm Adjustment Capability	No	Yes
Remote Accessibility	Yes	Yes

5.8. Summary of Performance Testing

Aulisa Multiple Patient Digital Vital Sign Monitoring System is a medical device stand-alone software; all testing was completed and the software has been verified and validated per FDA's Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Further, risk management assessment on the subject device was performed per ISO 14971, Medical Devices- Risk Management to verify that it does not raise any new safety and effectiveness issues in comparison to its predicate device.

Test results indicate that the subject device complies with its predetermined specifications and the applicable guidance document and standards.

5.9. Substantially Equivalent Conclusion

Based on the testing summarized in this 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.