July 23, 2024

AITRICS Co.,Ltd.
Dongyeop Kim
RA/QA manager
13F, 218, Teheran-ro, Gangnam-gu
Seoul, 06221
Korea, South

Re: K240756
Trade/Device Name: AITRICS-VC
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: PLB
Dated: March 18, 2024
Received: March 20, 2024

Dear Dongyeop Kim:

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.

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,

for Robert T. Kazmierski -S

LCDR Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics

and Monitoring Devices
OHT2: 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240756

Device Name
AITRICS-VC

Indications for Use *(Describe)*
The AITRICS-VC is stand-alone software intended to analyze patient data sourced from an EHR (Electronic Health Record) system and display data of in-hospital patients. It displays patient data whose vital signs, blood test results, or conventional early warning scores such as MEWS, NEWS, and qSOFA exceed predefined thresholds. It is not intended to replace bedside patient monitors or clinicians' clinical decision-making. It is not indicated for use in high-acuity environments like the ICU or operating rooms for acutely or critically ill patients. It may be used by clinicians to aid in understanding a patient's current condition and changes over time. The AITRICS-VC is solely indicated for use in the general ward of a hospital 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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510(k) Summary

This summary of safety and effectiveness information is prepared in accordance with the requirements of 21 CFR 807.92.

Date Prepared: March 20, 2024

I. Submitter

Applicant: AITRICS Co.,Ltd.
13F, 218, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea (06221)
Phone: +82 2 569 5507

Contact Person: Dongyeop Kim
RA/QA Manager

Prepared by:
Dongyeop Kim, RA/QA Manager
Sojeong Kim, RA manager
Sangjun Lee, RA Manager
Sun Young Kim, RA Manager

II. Device

Device Name: AITRICS-VC
Common Name: Cardiac monitor (including cardiotachometer and rate alarm)
Classification Name: Multivariate Vital Signs Index
Regulation Number: 870.2300
Product Code: PLB

III. Predicate Device

510(k) No.: K213335
Device Name: Capsule Surveillance System
Product Code: MWI

IV. Device Description

AITRICS-VC is a clinical decision support software that receives in-hospital patient information, including physiological parameters such as vital signs and blood test results from EHR and conducts rule-based calculations for conventional early warning scores, which include NEWS (National Early Warning Score), MEWS (Modified Early Warning Score), and qSOFA (quickSOFA).

The AITRICS-VC screens patients who meet predefined criteria based on single values of physiological parameters and early warning scores. It displays a multi-patient dashboard and detailed pages for individual patients via a web browser on clinicians' PCs.

V. Intended Use / Indications for Use

The AITRICS-VC is stand-alone software intended to analyze patient data sourced from an EHR (Electronic Health Record) system and display data of in-hospital patients. It displays patient data whose vital signs, blood test results, or conventional early warning scores such as MEWS, NEWS, and qSOFA exceed predefined thresholds. It is not intended to replace bedside patient monitors or clinicians' clinical decision-making. It is not indicated for use in high-acuity environments like the ICU or operating rooms for acutely or critically ill patients. It may be used by clinicians to aid in understanding a patient's current condition and changes over time. The AITRICS-VC is solely indicated for use in the general ward of a hospital environment.

[Comparison of Intended Use with Predicate Device]
Operational and technological characteristics form the basis for the determination of substantial equivalence of the subject device with the predicate device. The difference of technological characteristics does not raise new questions of safety and effectiveness and both devices have same intended use.

VI. Comparison of Technology Characteristics

The subject device and the predicate device are substantially equivalent in most technical characteristics. Both devices are used by clinicians and are utilized for analyzing and displaying patient data from EHR system in hospital settings. While there is a different technical characteristic for the output, the output of the subject device aligns with methods commonly used by clinicians, being encompassed by the methods of the predicate device, which are described as "clinical practices, protocols, and policies." Therefore, this difference raises no new questions of safety and effectiveness.

Attribute	Subject Device (AITRICS-VC)	Predicate Device
Product Code	PLB: Multivariate Vital Signs Index	MWI: Physiological Patient Monitor (without arrhythmia detection or alarms)
Indications for Use	The AITRICS-VC is stand-alone software intended to analyze patient data sourced from an EHR (Electronic Health Record) system and display data of in-hospital patients. It displays patient data whose vital signs, blood test results, or conventional early warning scores such as MEWS, NEWS, and qSOFA exceed predefined thresholds. It is not intended to replace bedside patient monitors or clinicians' clinical	The Capsule Surveillance is a clinical decision support device that integrates, analyzes, and displays data from multiple sources including medical devices and healthcare information systems. It uses standardized rules that are based on customers approved clinical practices, protocols, and policies to create clinically relevant alerts in health care facilities when used by clinical physicians or appropriate

Attribute	Subject Device (AITRICS-VC)	Predicate Device
	decision-making. It is not indicated for use in high-acuity environments like the ICU or operating rooms for acutely or critically ill patients. It may be used by clinicians to aid in understanding a patient's current condition and changes over time. The AITRICS-VC is solely indicated for use in the general ward of a hospital environment.	medical staff under the direction of physicians. It is not intended to replace clinicians' judgment, but rather to assist clinicians in making timely, informed, higher quality decisions. Capsule Surveillance may be configured for secondary monitoring and alerting intended to be relied upon in deciding to take immediate clinical action. Capsule Surveillance may also be configured for remote display of physiological data and alerts not intended to be relied upon in deciding to take immediate clinical action.
Intended User	Clinicians	Clinicians
Target Patients/ Environment of Use	Patients at general ward in hospital setting	Patients in hospital setting
Application Type	Remote display via a web browser	Two types; The workstation used exclusively in kiosk mode and the remote display via a web browser
Application Views	Two types; multi-patient simultaneous monitoring and detailed views/monitoring of single patients	Two types; multi-patient simultaneous monitoring and detailed views/monitoring of single patients
Data Input	EHR system via HL7 feed	EHR systems as well as medical devices via HL7 feed
Output	Patient information is displayed when patient data whose vital signs, blood test results, or conventional early warning scores exceed predefined thresholds.	Clinically relevant alerts are created by standardized rules that are based on customers approved clinical practices, protocols, and policies.
Performance data	Tests according to harmonized standards below. IEC 62304:2006/A1:2016 IEC 62366- 1:2015+AMDI:2020 IEC 60601-1-8	Tests according to harmonized standards below. IEC 62304:2006/A1:2016 IEC 62366- 1:2015+AMDI:2020 IEC 60601-1-8
Clinical data	Not require clinical data	Not require clinical data

VII. Performance Data

The AITRICS-VC has passed all non-clinical tests for demonstrated compliance with the harmonized standards below.

- IEC 62304 Ed 1.1 2015-06 | Medical device software – Software life cycle processes
- IEC 62366-1 Ed 1.1 2020-06 | Medical devices – Part 1 Application of usability engineering to medical devices
- IEC 60601-1-8 Ed 2.2 2020-07 | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

No new issues of safety or effectiveness are introduced as a result of using this device.

This device does not require clinical data.

VIII. Conclusions

The results of the substantial equivalence discussion including non-clinical tests demonstrate that the AITRICS-VC does not raise new questions of safety and effectiveness, performs as intended are substantially equivalent to the predicate device.