February 14, 2025

WARD 24/7 ApS
% Melissa DeHass
Principal Consultant
RQM+
2790 Mosside Boulevard Suite 800
Monroeville, Pennsylvania 15146

Re: K241958
Trade/Device Name: WARD-CSS (v1.2.x)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: July 3, 2024
Received: July 3, 2024

Dear Melissa Dehass:

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,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
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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)*
K241958

Device Name
WARD-CSS

Indications for Use *(Describe)*

WARD-CSS is a clinical decision support system that remotely integrates, analyzes and displays continuous vital sign data (via a mobile or web application) from medical devices for non-pediatric hospitalized patients within non-critical care units.

WARD-CSS uses a set of standardized rules based on scientific and clinical evidence to detect and alert on clinically relevant vital sign deviations when used by trained health care professionals in hospitals.

WARD-CSS is not intended to replace current monitoring practices or replace health care professionals' judgment. WARD-CSS is a tool intended to help health care professionals manage monitored patients and make clinical care decisions.
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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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

**DATE PREPARED**
December 20, 2024

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**DEVICE INFORMATION**

| | |
|---|---|
| **Proprietary Name/Trade Name** | WARD-Clinical Software Support (WARD-CSS) |
| **Common Name** | Monitor, physiological, patient (with arrhythmia detection of alarms) |
| **Regulation Number** | 870.2300 |
| **Class** | 2 |
| **Product Code** | MWI |
| **Premarket Review** | Traditional 510(k) |
| **Review Panel** | Cardiovascular |

**PREDICATE DEVICE IDENTIFICATION**
WARD-CSS is substantially equivalent to the following predicate:

| 510(k) Number | Predicate Device Name / Manufacturer | Primary Predicate |
|---|---|---|
| K213335 | Capsule Surveillance System / Capsule Surveillance Technologies, SAS /Capsule Tech, Inc. | ✓ |

**DEVICE DESCRIPTION**

WARD-CSS is a stand-alone software intended for use in continuous monitoring of patients and near real-time analysis of vital signs for the purpose of notifying healthcare professionals in case of clinically relevant vital sign deviations.

WARD-CSS utilizes knowledge-based algorithms to evaluate clinically relevant vital signs deviations to help drive clinical management.

The system is intended to be used as an adjunct to current monitoring practice in the general med/surg floors of the hospitals

The system assists healthcare professionals when monitoring patients on their wards by:

- Providing a real-time monitoring overview of vital signs for all patients.
- Alerting the healthcare professionals when a patient deteriorates.

The following types of alerts are detected by WARD-CSS in the vital sign data:

- Desaturation
- Hypertension
- Hypotension
- Bradypnea
- Tachypnea
- Tachycardia
- Bradycardia
- Hypotension and Bradycardia
- Hypotension and Tachycardia
- Bradypnea and Desaturation
- Fever

The WARD-CSS consists of a Mobile App, Web App and Backend Server. The Mobile App is used by healthcare professionals (HCPs) to monitor patients. The HCP will receive notifications of the alerts to their mobile phones. Within this app, the HCP can also document vital signs into an electronic health record system. The Web App is used by administrative users to manage hospitals, wards, users, and monitors. The Backend Server is used to receive and process all incoming data and manage all data used in the apps.

**Intended use/Indications for use**

WARD-CSS is a clinical decision support system that remotely integrates, analyzes and displays continuous vital sign data (via a mobile or web application) from medical devices for non-pediatric hospitalized patients within non-critical care units.

WARD-CSS uses a set of standardized rules based on scientific and clinical evidence to detect and alert on clinically relevant vital sign deviations when used by trained health care professionals in hospitals.

WARD-CSS is not intended to replace current monitoring practices or replace health care professionals' judgment. WARD-CSS is a tool intended to help health care professionals manage monitored patients and make clinical care decisions.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

WARD 24/7 ApS believes that the WARD-CSS is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions, and uses similar or identical materials, as the device cleared in K21335. The subject device has the same intended use and similar technological characteristics to the devices cleared in K213335, and the subject device has undergone testing to ensure the device is as safe and effective as the predicate.

| | **WARD-CSS (Subject Device)** | **Capsule Surveillance System (K213335) (Predicate Device)** | **Comments** |
|---|---|---|---|
| Product Code | MWI | MWI | Same |
| Regulation | 870.2330 | 870.2330 | Same |
| Indications for Use | WARD-CSS is a clinical decision support system that remotely integrates, analyzes and displays continuous vital sign data (via a mobile and web application) from medical devices for non-pediatric hospitalized patients within non-critical care units.<br><br>WARD-CSS uses a set of standardized rules based on scientific and clinical evidence to detect clinically relevant vital sign deviations (alerts) when used by trained health care professionals in hospitals.<br><br>WARD-CSS is not intended to replace health care professionals' judgment, but rather to assist health care professionals in making timely, informed, higher quality decisions. WARD-CSS is not intended to replace current monitoring practices but is intended to help drive clinical | Capsule Surveillance System 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 customer approved clinical practices, protocols and policies to create clinically relevant alerts in health care facilities when used by clinician physicians or appropriate medical staff under the direction of physicians. It is not intended to replace clinicians' judgement, 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 | Similar |

| | WARD-CSS (Subject Device) | Capsule Surveillance System (K213335) (Predicate Device) | Comments |
|---|---|---|---|
| | management. | remote display of physiological data and alerts not intended to be relied upon in deciding to take immediate clinical action. | |
| Intended User | Healthcare professionals | | Same |
| Intended Patient Population | Hospitalized adult patients (non-pediatric population) hospitalized patients within non-critical departments. | Hospital patients | Same, WARD-CSS and Capsule Surveillance System are utilized by adult patients not in the intensive care unit (ICU). |
| Patient Monitoring | Adjunctive | Adjunctive | Same |
| Vital Signs | • Heart rate<br>• Oxygen saturation<br>• Respiration rate<br>• Temperature<br>• Blood pressure | • Heart rate<br>• Oxygen saturation<br>• Respiration rate<br>• Temperature<br>• Blood pressure | Same |
| Platforms | Mobile App<br>Web App | Mobile App<br>Web App | Same |
| Algorithms | Threshold-based | Threshold-based | Same |
| Vital Sign Monitoring Resolution | 1-minute | | |
| Alerts | Direct detection from vital sign data | Direct detection from vital sign data | Same |

**SUMMARY OF NON-CLINICAL TESTING**

The following tests were performed to demonstrate safety based on current industry standards:

- Software Testing (IEC 62304)
- Human Factors (IEC 62366-1)

The results of these tests indicate that WARD-CSS is substantially equivalent to the predicate device, the Capsule Surveillance System (K213335).

**SUMMARY OF CLINICAL TESTING**

A literature review to support software algorithm development and determine the alert thresholds.

WARD-CSS reduces the number of alerts in comparison to standard patient monitors which alert immediately and repeatedly when a vital sign threshold is surpassed. (Standard patient monitors do not include a time duration component or any other alert filter).

WARD-CSS reduces the number of alerts in comparison to these standard patient monitors (indicating a basic threshold) by:

1) the introduction of a '**time duration'** for a threshold to be surpassed within the alerting condition
2) additional '**alert filters**' after the detection of the alerting conditions:
    1. Reissue time filter: an alert of the same type is not allowed to trigger again within a specific time duration (in order to reduce the amount of alerts when a patient is continuously fulfilling an alerting condition).
    2. Prioritization filter: an alert of lower priority is not allowed to trigger when an alert of higher priority is already active (this logic is only valid within the same alert groups like desaturation, bradycardia, tachycardia, hypertension, hypotension).

The combination of the '(**alert)time duration**' and '**alert filters**', in addition to basic thresholds, theoretically lowers the number of alerts.

A retrospective analysis has been performed on four cohorts from prospective clinical safety studies conducted from 2020-2024 to measure the impact of these alert reduction methodologies.

The vital sign data of 1115 subjects (the number of subjects included in the WARD-CSS safety clinical studies) was primarily used to to confirm safety and not all data have been extracted for alert analysis.

Of the 1115 patients included in the safety studies, 794 patients were used to analyze the number of alerts. These patients are representative of both hospitalized medical and surgical cohorts.

Alert rates were analyzed for the three following cases:

- Thresholds only
- Thresholds with time durations
- Thresholds with time durations and alert filters (**WARD-CSS**)

In **Table 1** below, the median and interquartile range for these cases are shown for all alert groups and each individual (bucketed) alerting group. A mean value is added to the results when the median is zero.

**Table 1. Alert Reduction Analysis**

| Methodology | All alert groups | [Hypertension + Hypotension] | [Bradypnea + Tachypnea] | [Tachycardia + Bradycardia] | [Desaturation + Desaturation/ Bradypnea] | [Hypotension/Tachycardia + Hypotension/Bradycardia] |
|---|---|---|---|---|---|---|
| Only thresholds | 417.0 [177.9-831.5] | 0.0 [0.0-1.0] (mean 1.0) | 33.7 [6.8-157.9] | 11.9 [0.8-61.2] (mean 76.3) | 256 [86.5-560.3] | 0.0 [0.0-0.0] (mean 0.1) |
| Thresholds and time durations | 111 [26.5-338.3] | 0.0 [0.0-0.0] (mean .04) | 4.7 [0.3-37.4] | 0.0 [0.0-1.9] (mean 29.0) | 63.2 [9.2-227.6] | 0.0 [0.0-0.0] (mean 0.0) |
| Thresholds, time durations and alert filters (WARD-CSS) | 9.0 [3.8-18.1] | 0.0 [0.0-0.0] (mean 0.3) | 1.6 [0.3-4.9] | 0.0 [0.0-0.3] (mean 1.0) | 4.7 [1.3 - 11.5] | 0.0 [0.0-0.0] mean (0.0) |

The introduction of **time durations** gives a 74% reduction in alerts (over all alert types).
The **alert filters** reduce the alerts even further resulting in a total reduction of alerts by **97.8%** by WARD-CSS in comparison to patient monitors that alert only upon thresholds.

*WARD does not have any data within these studies on temperature, so it is not possible to calculate alert reduction numbers for fever (but the alert reduction follows the same methodologies).

Summary
WARD-CSS reduces alert numbers compared to alert systems without- or with artefact removal.

**CONCLUSION**

Based on the testing performed, including software verification, bench performance testing, and clinical testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The proposed WARD-CSS software and the Capsule Surveillance System, cleared under K213335 have the same intended use and indications, similar technological characteristics, and the same principles of operation. Thus, the proposed WARD-CSS software is substantially equivalent to the predicate device.