August 24, 2023

Current Health Ltd
Giovanni Maggi
Regulatory Affairs Manager
The Stamp Office, Level 3, 10 Waterloo Place
Edinburgh, EH1 3EG
United Kingdom

Re: K231506
Trade/Device Name: Current Health System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MSX, FLL, DQA, BZQ, DRG, BZG
Dated: July 28, 2023
Received: July 28, 2023

Dear Giovanni Maggi:

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 Shruti N. Mistry -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and 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)*
K231506

Device Name
Current Health System

Indications for Use *(Describe)*

The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic monitoring of patients aged 14 years old and above in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals.

The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated.

The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters:

- Pulse rate
- Oxygen saturation
- Temperature
- Movement

The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring of:
- Respiration rate
- Non-invasive blood pressure
- Lung function & spirometry
- Weight

The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The Current Wearable Health Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor.

The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

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.

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Special 510(k) Summary

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirement of 21 CFR 807.92

Submitter Information:	
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Establishment Registration Number:	3015134004
Owner/Operator Number:	10059040
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Contact:	Giovanni Maggi Regulatory Affairs Manager
E-mail:	giovanni.maggi@currenthealth.com
Date of Summary:	27-Jul-2023

Device Information:

Below summarises the Device Classification information regarding the Current Health System.

Device Proprietary Name	Current Health System
Common Name:	Remote Patient Monitor
Trade Name:	Current Wearable Health Monitoring System
Product Code(s):	MSX; FLL; DQA; BZQ; DRG; BZG (see below)

Primary Product Code

Regulation Number (21 CFR)	Device	Product Class	Product Code	Classification Panel
870.2300	System, Network and Communication, Physiological Monitors	Class II	MSX	Cardiovascular

Secondary Product Codes

Regulation Number (21 CFR)	Device	Device Class	Product Code	Classification Panel
880.2910	Thermometer, Electronic, Clinical	Class II	FLL	General Hospital

870.2700	Oximeter	Class II	DQA	Cardiovascular
868.2375	Monitor, Breathing Frequency	Class II	BZQ	Anaesthesiology
870.2910	Transmitters and Receivers, Physiological Signal, Radiofrequency	Class II	DRG	Cardiovascular
686.1840	Spirometer, Diagnostic	Class II	BZG	Anaesthesiology

Substantial Equivalence

Manufacturer	Trade Name	Regulation & Product Code	510(k) Number
Current Health Ltd	Current Wearable Health Monitoring System	MSX; FLL; DQA; BZQ; DRG; BZG	K222550

Referenced Device

Manufacturer	Trade Name	Regulation & Product Code	510(k) Number
Draeger	Infinity Acute Care System Monitoring Solution (IACS)	MHX; BZQ; CCK; DQA, DRT; DSK; DXN; FLL; FLS; MLD; MSX	K113798

Submission Description

This Special 510(k) covers an extension of the age range to 14 years old and above patients on the software platform and G2 wearable of the Current Health System. This was also presented in the Q-Submission, Q212340.

There are no significant changes presented to the other software components previously cleared in K191272 – specifically, there is no change to the display of data from the wearable or how alarms are presented/notified to the healthcare professional. There are no changes to the wearable hardware component, as cleared in 510(k) K210133. There are no changes to the alarms system, as cleared in 510(k) K222550. Well-established methods have been used to evaluate the change and the data to be reviewed is provided in a summary in this submission.

Well-established methods have been used to evaluate the change and the date to be reviewed is provided in a summary in this submission.

Device Description

General Description

The Current Wearable System is a remote patient monitoring system that consists of a monitoring device (the wearable) worn on the upper arm by 14 years old and above patients, a software platform (containing the alarming system) and a user interface to allow presentation of vital signs data both on mobile devices and web-based dashboard. The Current Wearable System is also integrated with third-party devices for displaying and monitoring physiological signs.

The Wearable is intended to continuously monitors physiological vital sign data from the person being monitored and securely transmit the encrypted data via the home hub to the secure server. The wearable is

intended for use in professional healthcare facilities, such as hospitals or skilled nursing facilities, or the home by trained healthcare professionals.

The healthcare professional can securely access the patient physiological signs remotely via a mobile application or a web-interface which is also intended to provide visual and audible physiologic multi-parameter alarms.

Intended / Indications for Use

The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic monitoring of patients aged 14 years old and above in professional healthcare facilities, such as hospitals or skilled nursing facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals.

The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated.

The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters:

- Pulse rate
- Oxygen saturation
- Temperature
- Movement

The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring of the following parameters of:

- Respiration rate
- Non-invasive blood pressure
- Lung function & spirometry
- Weight

The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The Current Wearable Health Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life-threatening arrhythmias e.g., very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor.

The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

Comparison with the Predicate and Previously Cleared Device

The candidate device is substantially equivalent to the predicate, K222550, the Current Health Wearable Monitoring System and a comparison of the key characteristics is summarised in Table 1.

Characteristic	Current Health Wearable Monitoring System with Modification	Current Health Wearable Monitoring System K222550 (Primary Predicate)	Draeger IACS K113798 (Referenced Device)	Equivalence with Primary Predicate
Device Name	Current Health Monitoring System	Current Health Monitoring System	Infinity Acute Care System Monitoring Solution (IACS)	Equivalent

Characteristic	Current Health Wearable Monitoring System with Modification	Current Health Wearable Monitoring System K222550 (Primary Predicate)	Draeger IACS K113798 (Referenced Device)	Equivalence with Primary Predicate
Manufacturer	Current Health Ltd	Current Health Ltd	Draeger	Equivalent
Device Classification	II	II	II	Equivalent
Primary Product Code	MSX	MSX	MHX	Equivalent
Secondary Product Code	FLL; DQA; BZQ; DRG	FLL; DQA; BZQ; DRG	BZQ; CCK; DQA, DRT; DSK; DXN; FLL; FLS; MLD; MSX	Equivalent
Target Population	14 years and above	Adult	Adult, Paediatric and Neonatal	Substantially equivalent
Indications for Use	The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic monitoring of patients aged 14 years old and above in professional healthcare facilities, such as hospitals or skilled nursing facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals. The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated. The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters: • Pulse rate	The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals. The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated.	The IACS Monitoring Solution is a combination of two devices; Infinity M540 patient monitor with Infinity M500 docking station integrated with the Infinity C500 Medical Cockpit or optional C700 (larger screen size) Medical Cockpit and respective software. The IACS is intended for multi-parameter, physiologic patient monitoring of adult, pediatric and neonatal patients in environments where patient care is provided by trained healthcare profess sionals. The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and	Substantially Equivalent

Characteristic	Current Health Wearable Monitoring System with Modification	Current Health Wearable Monitoring System K222550 (Primary Predicate)	Draeger IACS K113798 (Referenced Device)	Equivalence with Primary Predicate
	• Oxygen saturation • Temperature • Movement The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring of the following parameters of: • Respiration rate • Non-invasive blood pressure • Lung function & spirometry • Weight The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms. The Current Wearable Health Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life-threatening arrhythmias e.g., very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor. The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.	The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters in adults: • Pulse rate • Oxygen saturation • Temperature • Movement The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring of the following parameters in adults, of: • Respiration rate • Non-invasive blood pressure • Lung function & spirometry • Weight in adults The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms. The Current Wearable Health Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life-threatening arrhythmias e.g., very	displays. The transfer of this data is accomplished by the Infinity network. The Infinity M540 is intended for the monitoring of multi-parameter, physiological patient information obtained from connected hardware in environments where patient care is provided by trained healthcare professional. The M540 is intended to monitor one patient at a time.	

Characteristic	Current Health Wearable Monitoring System with Modification	Current Health Wearable Monitoring System K222550 (Primary Predicate)	Draeger IACS K113798 (Referenced Device)	Equivalence with Primary Predicate
		fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor. The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.		
Intended user/Location	Professional healthcare facilities & home environments	Professional healthcare facilities & home environments	Professional healthcare facilities	Equivalent
Site of application	Wearable monitor upper arm with a strap	Wearable monitor upper arm with a strap	Wearable monitor	Equivalent
Wearable physiological monitoring	Pulse rate; Oxygen saturation; Temperature; Respiration Rate; Movement	Pulse rate; Oxygen saturation; Temperature; Respiration Rate; Movement	Heart rate; Arrhythmia (adult and pediatric only); 12-lead analysis; ST segment analysis including TruST® (adult and pediatric only); 12-lead ST segment analysis (adult and pediatric only); Apnea; Respiration rate; Invasive pressure; Non-invasive pressure;	Equivalent

Characteristic	Current Health Wearable Monitoring System with Modification	Current Health Wearable Monitoring System K222550 (Primary Predicate)	Draeger IACS K113798 (Referenced Device)	Equivalence with Primary Predicate
			Temperature; Cardiac output; Arterial oxygen saturation (SpO 2); Pulse rate; Perfusion Index (P1); Total hemoglobin (SpHb) – adult and pediatric only; Total oxygen content (SpCO) – adult and pediatric only; Methemoglobin saturation (SpMet); Pleth variability index (PVI); Mainstream etCO2	
Instructions of use	Instructions for use included that includes graphical instructions, text and relevant warnings and cautions	Instructions for use included that includes graphical instructions, text and relevant warnings and cautions	Instructions for use included that includes graphical instructions, text and relevant warnings and cautions	Equivalent
Sterile	No	No	No	Equivalent
Re-usable	Yes	Yes	Yes	Equivalent
Generation of Alarms	The alarm system inputs data from the patient facts database (data from the wearable, existing integrated devices and from a broader range of patient observations) to generate appropriate alarms, notifications and quantified notes to the clinical care team	The alarm system inputs data from the patient facts database (data from the wearable, existing integrated devices and from a broader range of patient observations) to generate appropriate alarms, notifications	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Equivalent

Characteristic	Current Health Wearable Monitoring System with Modification	Current Health Wearable Monitoring System K222550 (Primary Predicate)	Draeger IACS K113798 (Referenced Device)	Equivalence with Primary Predicate
		and quantified notes to the clinical care team		
Display of Alarms on User Interface	Alarms are presented through visual and audible notifications on the web dashboard and mobile apps	Alarms are presented through visual and audible notifications on the web dashboard and mobile apps	Alarms are presented through user interface displayable at bedside	Equivalent

Table 1: Comparison of characteristics between the Modified System and the Predicate Systems.

Technological Characteristics

The proposed modification to extending the age range to 14 years old and above patients on the Current Health Wearable Monitoring System has identical indications for use, operating principles, performance, and technical specification as the predicate device, the Current Health Wearable Monitoring system.

Summary of Non-Clinical Tests (Performance data)

The performance of the modification is identical to the predicate and previously cleared device in terms of technical specification and safety.

Summary of Animal & Clinical Studies

Substantial equivalence is based on an assessment of non-clinical performance data and no animal or clinical performance data is included.

Conclusion

Based on the information presented in this Special 510(k) submission, the Current Health Wearable Monitoring System with the modified intended patient population, is substantially equivalent to the predicate device (Current Health Wearable Monitoring System) in terms of safety, performance, functionality, and indications for use and is as safe and effective as the predicate device for its intended use.