September 3, 2021

Current Health
Phil Bromley
VP/QA/RA
Playfair House, 6 Broughton Street Lane
Edinburgh, EH 1 3LY
United Kingdom

Re: K210133
Trade/Device Name: Current Health Monitoring System Gen 2 (G2)
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: May 18, 2021
Received: June 4, 2021

Dear Phil Bromley:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Current Health Monitoring System Gen 2

Indications for Use *(Describe)*

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 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, in adults, 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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K210133 510(k) Summary

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

Submitters Information:	
Name:	Current Health Ltd.
Address:	Playfair House 6A Boughton Street Lane Edinburgh EH1 3LY United Kingdom
Establishment Registration Number:	3015134004
Owner/Operator Number:	10059040
Phone:	+44 (0) 131 285 8101
Contact:	Phil Bromley VP of QA/RA
E-mail:	phil.bromley@currenthealth.com
Date of Summary:	26-Apr-21

Device Information:

Below summarises the Device Classification information regarding the Current Wearable Health Monitoring System, Gen 2, Device.

Device Proprietary Name	Second Generation (G2) Wearable
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	K191272

Device Description

This 510(k) for the introduction of the Second Generation (Gen 2) wearable is component of the Current Wearable Health Monitoring System. There is no substantial change to the healthcare professional monitoring applications (mobile apps and web-dashboard) and data infrastructure (secure server) with this 510(k) submission.

General Description

The Current Wearable Health Monitoring System is a remote patient monitoring system that consists of a single monitoring device (the wearable) worn on the upper arm by adult patients (aged 18 years old and over), a software platform (containing an alarming system) and a user interface to allow presentation of vital signs data both on mobile devices and a central station. The Current Wearable Health Monitoring System is also integrated with specific devices for monitoring of blood pressure, spirometry, lung function, and weight.

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.

It is intended to continuously monitor pulse rate (PR), oxygen saturation (SpO2), temperature (TEMP) and movement (MOVEMENT). Current is intended for intermittent or spot-checking monitoring of respiration rate (RESP), blood pressure (BP), spirometry and lung function, and weight (WEIGHT).

In the home environment, the patient will have responsibility for applying the device to their arm, charging the device, and plugging in the Homehub to mains power. The data will still be made directly available to healthcare professionals. These healthcare professionals will be at a remote location e.g., an office or within the hospital or could be with the patient in their own home.

Intended/ Indications for Use

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 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 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.

Substantial Equivalence

The candidate device is substantially equivalent to the predicate, K191272, the Current Health Wearable Monitoring System (Gen 1) and a comparison of the key characteristics is summarised in Table 1.

Characteristic	Current Health Gen 2 Wearable (Candidate)	Current Health Wearable Monitoring System K191272 (Predicate(	Equivalence
Device Name	Current Health Gen 2	Current Health Monitoring System	n/a
Manufacturer	Current Health Ltd	Current Health Ltd	n/a
Device Classification	II	II	Equivalent
Primary Product Code	MSX	MSX	Equivalent
Secondary Product Code	FLL; DQA; BZQ; DRG	FLL; DQA; BZQ; DRG	Equivalent
Indications for Use	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,	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,	Equivalent

Characteristic	Current Health Gen 2 Wearable (Candidate)	Current Health Wearable Monitoring System K191272 (Predicate(	Equivalence
	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 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 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.	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 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 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.	

Characteristic	Current Health Gen 2 Wearable (Candidate)	Current Health Wearable Monitoring System K191272 (Predicate(	Equivalence
Intended user/Location	Professional healthcare facilities & home environments	Professional healthcare facilities & home environments	Equivalent
Site of application	Upper arm with a strap	Upper arm with a strap	Equivalent
Wearable physiological monitoring	Pulse rate; Oxygen saturation; Temperature; Respiration Rate; Movement	Pulse rate; Oxygen saturation; Temperature; Respiration Rate; Movement	Equivalent
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	Equivalent
Sterile	No	No	Equivalent
Re-usable	Yes	Yes	Equivalent
Materials	Plastic case and ISO 10993-1:2018 compliant	Plastic case and ISO 10993-1:2018 compliant	Equivalent
Standards Applied	IEC 60601-1; IEC 60601-1-2; IEC 62304; IEC 80601-2-61; IEC 80601-2-56	IEC 60601-1; IEC 60601-1-2; IEC 62304; IEC 80601-2-61; IEC 80601-2-56	Equivalent

Table 1: Comparison of characteristics between Gen 2 and Gen 1 Wearable Devices

Technological Characteristics

The Gen 2 wearable device has identical indications for use, operating principles, performance, and technical specification as the predicate device, the Current Health Wearable Monitoring system (Gen 1) wearable.

The PPG sensor in the Gen 2 wearable device is identical to the sensor used in the Gen 1 wearable for equivalent sensing of oxygen saturation and pulse rate and it is used in the same way. The Gen 2 wearable has different analogue front-end electronics and sampling rate to the Gen 1 wearable however this has been demonstrated to be equivalent through the performance testing presented in this 510(k). Temperature sensing in Gen 2 uses a different thermocouple which has been demonstrated to have equivalent performance to the Gen 1 temperature sensor in terms of accuracy and tolerance. Reparatory rate for Gen 2 is measured using the same technical method with different motion sensors and these have been demonstrated to have equivalent performance during performance testing.

Summary of Non-Clinical Tests (Performance data)

The performance of the Gen 2 wearable is identical to the predicate device in terms of technical specification and safety. The primary differences are that the Gen 2 is smaller than the Gen 1 with the ability to charge the device on-arm while in use.

Verification and validation activities established the safety and performance of the Gen 2 based on the following tests, which were all passed:

Electrical Safety: The Current Health Gen 2 was tested to confirm that it met the applicable standards for electrical safety (IEC 60601-1)

Electromagnetic compatibility: The current Health Gen 2 was tested to confirm it meets the applicable standards for electromagnetic compatibility (EMC) (IEC 60601-1-2)

Pulse Rate Testing: Validation of the accuracy of pulse rate monitoring – the Current Health Gen 2 was tested to confirm the accuracy of pulse rate monitoring of the system in accordance with ISO 80601-2-61 and the FDA Pulse Oximeters – Premarket Notification Submissions: Guidance for Industry and FDA Staff. 2007

SpO2 Testing: Validation of the accuracy of SpO2 monitoring – Ensure the accuracy and communication of the SpO2 functions of the Current Health Gen 2 wearable as per ISO80601-2-61 and the FDA SpO2 guidance; Pulse Oximeters-Premarket Notification Submissions Guidance for Industry and Food and Drug Staff, March 4, 2013

Respiratory Rate Testing: Ensure accuracy of the Current Health Gen 2 measurement of respiration rate in comparison to respiration rate measured via end-tidal CO2 in a variety of postures

Temperature Measurement Accuracy: The Current Health Gen 2 was tested to confirm the Temperature Measurement Accuracy of the system in compliance with ISO 80601-2-56

Device Ship/Transport Testing: Ensure device, enclosed in the selected shipping container, meets ASTM D7386 specifications.

Biocompatibility Testing: Testing and analysis of the Current Health Gen 2 has demonstrated compliance to ISO 10993-1: Biological evaluation of medical devices – Guidance

System Verification and Validation Testing: The system verification and validation testing was performed to verify the software and firmware of the Current Health Gen 2. This included testing of integration and interoperability of the peripheral devices for blood pressure and weight.

Software Verification and Validation Testing: Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator or a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

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

The Gen 2 wearable device has identical indications for use, operating principles, performance, and technical specification as the Current Health Wearable Monitoring system (Gen 1) wearable.

Based on the information presented in this 510(k) premarket notification, the Current Health Second Generation (Gen 2) wearable device is substantially equivalent to the predicate device (Current Health Wearable Monitoring System (Gen 1)) in terms of safety, performance, functionality and indications for use and is as safe and effective for its intended use.