



July 12, 2019

Current Health Ltd.
Edwin Lindsay
QA/RA Manager
Playfair House
12A Broughton Street Lane
Edinburgh, EH1 3LY
United Kingdom

Re: K191272

Trade/Device Name: Current Wearable Health Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, FLL, DQA, BZQ, DRG, BZG
Dated: May 6, 2019
Received: May 13, 2019

Dear Edwin Lindsay:

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 Nicole Goodsell
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

Indications for Use

510(k) Number (if known)

Device Name

Current Wearable Health Monitoring System

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“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.”

**Current Health Ltd.
Traditional 510(k)**

For Current Wearable Health Monitoring System

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Current Health Ltd

Submitter's Address:

Playfair House,
12A Broughton Street Lane
Edinburgh
EH1 3LY

Telephone: +44 (0) 131 560 1137

Establishment Registration Number:

3015134004

Contact Person:

Edwin Lindsay

Telephone +44 (0) 7917134922

Date Prepared:

6th May 2019

Note: snap40 Ltd has recently changed their name to Current Health Ltd.

Current Health Ltd. Traditional 510(k)

For Current Wearable Health Monitoring System

Below summaries the Device Classification Information regarding the Current Wearable Health Monitoring System:

Primary Product Code:

Regulation Number	Device	Device Class	Product Code	Classification Panel
870.2300	System, Network and Communication, Physiological Monitors	Class 2	MSX	Cardiovascular

Secondary Product Codes:

Regulation Number	Device	Device Class	Product Code	Classification Panel
880.2910	Thermometer, Electronic, Clinical	Class 2	FLL	General Hospital
870.2700	Oximeter	Class 2	DQA	Cardiovascular
868.2375	Monitor, Breathing Frequency	Class 2	BZQ	Anesthesiology
870.2910	Transmitters and Receivers, Physiological Signal, Radiofrequency	Class 2	DRG	Cardiovascular
868.1840	Spirometer, Diagnostic	Class 2	BZG	Anesthesiology

Device Trade Name:

Current Wearable Health Monitoring System

Device Common Name:

Current Wearable Health Monitoring System

Intended/ Indications 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

Current Health Ltd. Traditional 510(k)

For Current Wearable Health Monitoring System

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.

Current Health Ltd. Traditional 510(k)

For Current Wearable Health Monitoring System

Summary of Substantial Equivalence:

The following predicate devices have been chosen that the Current Wearable Health Monitoring System can claim equivalence with and these are detailed below

General Comparison

Property	<i>Proposed Device</i> Current Wearable Health Monitoring System	<i>Primary Predicate</i> Current Wearable Health Monitoring System	<i>Secondary Predicate</i> Spirobank G	<i>Secondary Predicate</i> VivaLnk Fever Scout	Comment
Common Name	System, Network and Communication, Physiological Monitors	System, Network and Communication, Physiological Monitors	Spirometer, Diagnostic	Thermometer, Electronic, Clinical	N/A
Device Manufacturer	Current Health Ltd	Current Health Ltd	M.I.R Medical International Research	VivaLnk Inc	N/A
Device Classification	II	II	II	II	N/A
510(k) Number	N/A	K190073	K072979	K181013	N/A
Primary Product Code	MSX	MSX	BZG	FLL	N/A
Secondary Product Code	FLL DQA BZQ DRG BZG	FLL DQA BZQ DRG	N/A	N/A	N/A
Target Population	Adult	Adult	Adult	Adult & Children	The proposed device and predicates are identical
Environment	Professional Healthcare Facilities & Home	Professional Healthcare Facilities & Home	Professional Healthcare Facilities & Home	Professional Healthcare Facilities & Home	The proposed device and predicates are identical

Current Health Ltd. Traditional 510(k)

For Current Wearable Health Monitoring System

Property	<i>Proposed Device</i> Current Wearable Health Monitoring System	<i>Primary Predicate</i> Current Wearable Health Monitoring System	<i>Secondary Predicate</i> Spirobank G	<i>Secondary Predicate</i> VivaLnk Fever Scout	Comment
Intended Use/ Indication for Use	<p>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.</p> <p>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.</p> <p>The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters</p>	<p>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.</p> <p>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.</p> <p>The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters</p>	<p>The Spirobank G spirometer is intended to be used by a physician or by a patient under the instruction of a physician or paramedic. The device is intended to test lung function and can make spirometry testing in people of all ages, excluding infants and neonates. It can be used in any setting.</p>	<p>The wireless Fever Scout Continuous Monitoring thermometer is a non-invasive and re-usable electronic device for home use and a non-invasive and single patient use in the home. This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.</p>	<p>The intended use and indications for use of the proposed device and the primary predicate are identical in that they both offer multi-parameter physiologic monitoring in professional healthcare facilities and the home.</p> <p>The intended use and indications for use of the proposed device and the secondary predicate, the Spirobank G, are the same in that they both monitor lung function and spirometry.</p> <p>The intended use and indications for use of the proposed device and the secondary predicate, the VivaLnk Fever Scot, are the same in that they both monitor temperature.</p>

**Current Health Ltd.
Traditional 510(k)**

For Current Wearable Health Monitoring System

Property	<i>Proposed Device</i> Current Wearable Health Monitoring System	<i>Primary Predicate</i> Current Wearable Health Monitoring System	<i>Secondary Predicate</i> Spirobank G	<i>Secondary Predicate</i> VivaLnk Fever Scout	Comment
	<p align="center">in adults:</p> <p align="center">Pulse rate Oxygen saturation Temperature Movement</p> <p>The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring, in adults, of:</p> <p align="center">Respiration rate Non-invasive blood pressure Lung function & spirometry Weight</p> <p>The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.</p> <p>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</p>	<p align="center">in adults:</p> <p align="center">Pulse rate Oxygen saturation Temperature Movement</p> <p>The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring of respiration rate, non-invasive blood pressure and weight in adults.</p> <p>The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.</p> <p>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</p>			

**Current Health Ltd.
Traditional 510(k)**

For Current Wearable Health Monitoring System

Property	<i>Proposed Device</i> Current Wearable Health Monitoring System	<i>Primary Predicate</i> Current Wearable Health Monitoring System	<i>Secondary Predicate</i> Spirobank G	<i>Secondary Predicate</i> VivaLnk Fever Scout	Comment
	<p>monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor.</p> <p>The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.</p>	<p>Health Monitoring System is not a substitute for an ECG monitor.</p> <p>The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.</p>			

There are no technical differences.

Current Health Ltd.

Traditional 510(k)

For Current Wearable Health Monitoring System

Device Description:

The Current Wearable Health Monitoring System consists of a single monitoring device worn on the upper arm, 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 devices for monitoring of blood pressure, spirometry & lung function, and weight.

The system is intended to continuously monitor adult patient vital signs 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. 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 & lung function, and weight (WEIGHT).

While the wearable device monitors skin temperature, an additional adhesive axillary sensor can be used to monitor axillary temperature.

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. However, 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.

Technological Characteristics:

A comparative review of the Current Wearable Health Monitoring System with the predicate device found that the technology, mode of operation, and general principles for treatment with this device were substantially equivalent to the predicate device.

Non-Clinical Tests (Performance/Physical Data):

The Current Wearable Health Monitoring System was evaluated for its safety and effectiveness based on the following testing:

Test Name	Test Description	Results
Electrical Safety	The Current Health System was tested to confirm that it met the applicable standards for electrical safety (IEC 60601-1)	Passed
EMC	The Current Health System was tested to confirm that it met the applicable standards for electromagnetic compatibility (EMC) (IEC 60601-1-2)	Passed
Qi Charger Testing	The Current Health Wearable was tested to confirm the device could be charged using the Qi Charger	Passed

**Current Health Ltd.
Traditional 510(k)**

For Current Wearable Health Monitoring System

Test Name	Test Description	Results
Environment Testing	The Current Health System was tested to confirm the storage and operating temperature ranges.	Passed
Alarm Testing	<p>The Current Health System was tested to confirm that it met the applicable standards for basic safety and essential performance for alarm systems (IEC 60601-1-8)</p> <p>Alarm Function Verification Tests for each parameter function were performed.</p>	Passed
Pulse Rate Testing Validation of the accuracy of pulse rate monitoring	The Current Health System 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	Passed
Battery Testing	The Current Health Wearable Device Battery Life testing was performed to determine the battery life of the Wearable Device while operating in various modes as well as time to fully charge.	Passed
PDU Buffering Time Testing	The Current Health system was tested to evaluate the difference between the theoretical maximum PDU buffering time and the observed maximum PDU buffering time.	Passed
Usability Testing	The Current Health System was assessed with regards to usability for compliance with IEC 62366 - Medical devices - Application of usability engineering to medical devices and IEC 60601-1-11	Passed
Device Ship/Transport Testing	Ensure device, enclosed in the selected shipping container, meets ASTM D4169 specifications.	Passed
Biocompatibility Testing	Testing and analysis of the Current Health System has demonstrated compliance to ISO 10993-1: Biological evaluation of medical devices – Guidance	Passed

Current Health Ltd. Traditional 510(k)

For Current Wearable Health Monitoring System

Test Name	Test Description	Results
SpO2 Testing Validation of the accuracy of SpO2 monitoring	Ensure the accuracy and communication of the SpO2 functions within the Current Health system 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	Passed
Respiratory Rate Testing	Ensure accuracy of the Current Health system measurement of respiration rate in comparison to respiration rate measured via end-tidal CO2 in a variety of postures	Passed
Temperature Measurement Accuracy	The Current Health System was tested to confirm the Temperature Measurement Accuracy of the system in compliance with ISO 80601-2-56	Passed
Wireless Radio Communication (Wireless Coexistence Testing)	The Current Health System was tested to ensure device can communicate via wireless radio in its intended environment	Passed
System Verification and Validation Testing	The system verification and validation testing was performed to verify the software and firmware of the Current Health System. This included testing of integration and interoperability of the peripheral devices for blood pressure, axillary temperature, lung function & spirometry and weight.	Passed

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.

Animal Studies

No animal studies were conducted as part of submission to prove substantial equivalence.

Current Health Ltd.
Traditional 510(k)

For Current Wearable Health Monitoring System

Clinical Studies

No clinical studies were conducted as part of submission to prove substantial equivalence.

Safety and Effectiveness/Conclusion:

Based on the information presented in these 510(k) premarket notifications the Current Wearable Health Monitoring System is considered substantially equivalent. The Current Wearable Health Monitoring System is as safe and effective as the currently marketed predicate devices.

Based on testing and comparison with the predicate devices, the Current Wearable Health Monitoring System indicated no adverse indications or results. It is our determination that the Current Wearable Health Monitoring System is safe, effective and performs within its design specifications and is substantially equivalent to the predicate device.