November 18, 2022

Chronisense Medical, Ltd.
% Allison Komiyama
President, AcKRS
Rqm+
2251 San Diego Ave.
Ste B-257
San Diego, California 92110

Re: K220351
Trade/Device Name: Polso Watch
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: October 14, 2022
Received: October 31, 2022

Dear Allison Komiyama:

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,

James J. Lee -S

James J. Lee, Ph.D.
Divisiion Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K220351

Device Name
Polso™ Watch

Indications for Use *(Describe)*
The Polso™ Watch is a wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, and respiration rate. The Polso™ Watch is a prescription-use device intended for spot-checking measurements of patients aged 18 years and older in the home use environment in non-motion conditions.
The device is not intended to be used for diagnostic applications nor is it intended to independently guide treatment decisions. The device is not an apnea monitor. Physiological parameters will later be provided for remote review by a clinician.

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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510(k) Summary
K220351

DATE PREPARED
November 10, 2022

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Polso™ Watch
Common Name:	Oximeter, breathing frequency monitor
Regulation Number:	21 CFR 870.2700, 21 CFR 868.2375
Class:	II
Product Code:	DQA, BZQ
Premarket Review:	Anesthesiology
Review Panel:	OHT1/ Division of Anesthesia, Respiratory, and Sleep Devices (DHT1C)

PREDICATE DEVICE IDENTIFICATION
The Polso™ Watch is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*	*Reference Device*
K181352	Loop System / Spry Health, Inc.	✓	
K181956	Masimo MightySat Rx Fingertip Pulse Oximeter / Masimo Corporation		✓

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

The Polso™ Watch is a wearable device intended for non-invasive measurements and display of pulse rate (PR), blood oxygen saturation (SpO2), and respiration rate (RR). It is a prescription-use device intended for spot-checking measurements of patients aged 18 years and older in the home use environment in non-motion conditions. The device is not intended to be used for diagnostic applications nor it is intended to independently guide treatment decisions.

The Polso™ Watch is worn on the wrist and features sensors that are located facing the radial artery and at the dorsal wrist, for measurement of physiological information. The Polso™ Watch screen displays measurements, battery status, Bluetooth connection status, and time of day. The Control Button allows navigation between different display screens. The Polso™ Watch is available in sizes S, M and L to cover wrist sizes from 5.5" to 8.4" circumference. The Polso™ Watch is powered by a rechargeable lithium-polymer battery.

The Polso™ Watch is paired with a companion mobile application (Polso™ App) on an Android device. The App is used to set up the Polso™ Watch and to review up to 3 months of measurement data.

INDICATIONS FOR USE

The Polso™ Watch is a wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2), pulse rate, and respiration rate. The Polso™ Watch is a prescription-use device intended for spot-checking measurements of patients aged 18 years and older in the home use environment in non-motion conditions. The device is not intended to be used for diagnostic applications nor is it intended to independently guide treatment decisions. The device is not an apnea monitor. Physiological parameters will later be provided for remote review by a clinician.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

ChroniSense Medical, Ltd. believes that the Polso™ Watch is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use as the device cleared in K181352. Both devices are intended to measure pulse rate (PR), blood oxygen saturation (SpO2), and respiration rate (RR) in non-moving adult patients in home environments. The intended population for the subject device includes transitional adolescents, aged 18 to 21. For the intended use of the device, the inclusion of this pediatric population does not raise new questions of safety or effectiveness and is validated by two clinical studies.

The subject device has a similar design as the device cleared in K181352. Both devices have a 'watch' form factor that is worn on the wrist, with measurements displayed on the wearable

device and transmitted to another location (mobile app, web interface) for additional monitoring. Both devices have internal rechargeable batteries.

The subject device uses similar technology for measurements as the device cleared in K181352. Both devices have PPG sensors to gather data from peripheral arteries.
The main technological differences of the subject device, as compared to the predicate device cleared in K181352, are:

- Sampling frequency. The subject device is intended for spot-checking under non-motion conditions, meaning the user determines when to check for measurements. By contrast, the predicate device is designed for nearly continuous measuring and recording of physiological data when the patient is not in motion. The difference in sampling frequency does not raise new questions of safety or effectiveness.
- SpO2 accuracy. The subject device display range is 70% to 100% and accuracy is 2% Arms while the predicate device has the same display range, but accuracy is 3% Arms. This difference is within the values of the predicate device and is therefore considered equivalent.
- RR range. The subject device has a RR range of 5-45 BPM while the predicate device has a RR range of 4-40 RPM. This technical difference has undergone testing to ensure the subject device is as safe and effective as the predicate device.
- Data communication. Both devices transmit measurements wirelessly to either a mobile device (subject device) or a web server (predicate). The subject device uses Bluetooth low energy (BLE) methodology while the predicate uses a cellular connection. This technical difference has undergone testing to ensure the subject device is as safe and effective as the predicate device.
- Data communication to physician. The predicate device automatically transmits collected data to a remote server for review by a physician, while the subject device stores data on the Watch and the mobile application. Review of the data by the physician is done during clinic visits or data is communicated remotely to the physician by the patient. This technical difference has undergone human factor testing to ensure the subject device is as safe and effective as the predicate device. In addition, the reference device cleared in K181956 uses similar spot-checking technology in a home use environment. Collected data is stored on the reference device. Bluetooth communication to a mobile app is an optional feature for data transfer and review by a physician.

The Polso™ Watch is substantially equivalent to the predicate devices based on the information summarized in the following table:

	Subject Device	***Predicate Device***	***Reference Device***
	ChroniSense Medical Ltd Polso™ Watch K220351	Spry Health, Inc. Loop System K181352	Masimo Corporation Masimo MightySat Rx Fingertip Pulse Oximeter K181956
Indications for Use	The Polso™ Watch is a wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, and respiration rate. The Polso™ Watch is a prescription-use device intended for spot-checking measurements of patients aged 18 years and older in the home use environment in non-motion conditions. The device is not intended to be used for diagnostic applications nor is it intended to independently guide treatment decisions. The device is not an apnea monitor. Physiological parameters will later be provided for remote review by a clinician.	The Loop System is intended for adult patients in the home environment for passive, non-invasive, intermittent data collection of physiological parameters that will later be transmitted to a web server for remote review by a clinician. The Loop System measures and records: • arterial oxygen saturation (SpO2) • heart rate (HR) • respiration rate (RR) All of these measurements are made when no motion is detected by the System. The Loop System device does not provide physiological alarms	The Masimo MightySat Rx Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments, and transport. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients.
Product Codes / Regulation Number	DQA / 21 CFR 870.2700 BZQ / 21 CFR 868.2375	DQA / 21 CFR 870.2700 BZQ / 21 CFR 868.2375	DQA / 21 CFR 870.2700 BZQ / 21 CFR 868.2375
Rx/OTC	Rx	Rx	Rx
Intended users	Adults (aged 18 and older)	Adults	Adults/pediatric (SpO2, pulse rate) Adults (respiration rate)
Intended use environments	Home environment	Home environment	Hospitals, hospital-type facilities, home environments, and transport
Technological Characteristics			
Device Components	• Polso™ Watch • Polso™ App • Polso™ Watch Charger Stand with micro USB cable and power adapter	• Loop band • Spry server • Charging station	• Fingertip device • Battery • Carrying case

Anatomical site of measurements	Wrist	Wrist	Finger
Sampling frequency	Spot-checking in non-motion conditions	Intermittent data collection when patient is not in motion	Spot-checking in non-motion and motion conditions
SpO_2 measurement method	Photoplethysmography	Photoplethysmography	Photoplethysmography
SpO_2 display range	70% to 100%	70% to 100%	70% to 100% (no motion)
SpO_2 Accuracy	2% A_{rms}	3% A_{rms}	2% A_{rms} (no motion)
Pulse rate / heart rate measurement method	Photoplethysmography	Photoplethysmography	Photoplethysmography
Pulse rate / heart rate display range	25-250 beats per minute (BPM)	25-250 BPM	25-240 BPM
Pulse rate / heart rate accuracy	3 BPM A_{rms}	3 BPM A_{rms}	3 BPM A_{rms}
RR measurement method	Photoplethysmography	Photoplethysmography	Photoplethysmography
RR display range	5-45 breaths per minute (BPM)	4-40 respirations per minute (RPM)	4-70 respirations per minute (RPM)
RR accuracy	3 BPM A_{rms}	3 RPM A_{rms}	3 RPM A_{rms}
Display	AMOLED color display	LED color display	OLED color display
Power source	Internal rechargeable battery	Internal rechargeable batteries	Two 1.5V AAA batteries
Data communication	Wireless (Bluetooth BLE pairing) with Android mobile device	Wireless (cellular connection) via charging station to Spry Server	Optional wireless (Bluetooth LE)

SUMMARY OF NON-CLINICAL TESTING

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

- Biocompatibility testing per ISO 10993-1, 10993-5, 10993-10
- Software V&V per IEC 62304
- Electrical Safety and Electromagnetic Compatibility testing per IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 62133, ISO 80601-2-61
- Compliance to CFR 47 Part 15 Subpart C for BLE transmission
- Bench performance testing for RR range and accuracy

The results of these tests indicate that the Polso™ Watch is substantially equivalent to the predicate device.

SUMMARY OF CLINICAL TESTING

Two clinical studies were conducted to demonstrate the performance of the Polso™ Watch. Evaluation included participants with a range of demographics including a mix of gender, skin tone (Fitzpatrick scale I-VI), age, and BMI (based on height and weight).

- SpO_2 and Pulse Rate Validation Study. The objective of this study was to validate the SpO_2 accuracy and the pulse rate accuracy of the Polso™ Watch pulse oximeter during non-motion conditions in 10 healthy adult subjects with a range of skin types (2 having a Fitzpatrick score of V or VI). The accuracy of the Polso™ Watch was compared to the gold standard, arterial blood samples assessed by SaO2 CO-Oximetry. Per FDA's request, data on two additional subjects with Fitzpatrick scores of IV and VI were provided to demonstrate the device works on the intended population.
- Respiration Rate Validation Study. The objective of this study was to validate the respiration rate accuracy of the Polso™ Watch pulse oximeter during non-motion conditions in 31 adult subjects with a range of skin types and health conditions. The accuracy of the Polso™ Watch was compared to manual, clinician-scored End Tidal Carbon Dioxide monitoring as the gold standard.

This testing was conducted in accordance with ISO 80601-2-61 *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*, and FDA's Guidance *Pulse Oximeters – Premarket Notifications Submissions.*

CONCLUSION

Based on the testing performed, including biocompatibility, software V&V, EMC and electrical safety, wireless transmission testing, 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 similar indications for use, technological characteristics, and performance characteristics for the proposed Polso™ Watch are assessed to be substantially equivalent to the predicate device.