June 7, 2021

Taiwan Scientific Corporation
D.C. Sun
General Manager
10F, 88-4, Ming-Chiuan Rd., Shin-Dian District
New Taipei, 23141
Taiwan

Re: K201914
Trade/Device Name: HRVWatch-Mini Wrist Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 31, 2021
Received: May 3, 2021

Dear D.C. Sun:

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

LT Stephen Browning
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)*
K201914

Device Name
HRVWatch-Mini Wrist Monitor

Indications for Use *(Describe)*
Indications for Use: Non-invasive measurement of systolic pressure (SYS), diastolic pressure (DIA), heart rate (HR), heart rate variability (HRV), and irregular heartbeats (IrrHB) for professionals at office or patients at home. The device is not intended for ambulatory use. The device has not been tested and it is not intended for pediatric use. The device provides a HRV parameter which is only mathematical analysis and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

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.

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5. 510(k) Summary

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of Safe Medical Devices Act (SMDA) and 21 CFR 807.92.

5.1 510(k) Number: k201914

5.2 Applicant Information:

Date Prepared: May 20, 2020
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5.3 Device Information:

Classification: DXN /Class II/870.1130
Trade Name: HRVWatch-Mini Wrist Monitor
Common Name: Non-invasive blood pressure meter system
Classification Name: Noninvasive blood pressure measurement system

5.4 Predicate Devices:

(1) HRVWatch Wrist Monitor K123130 (primary predicate device)
(2) Full Automatic (NIBP) Blood Pressure Monitor HL158UA K162338
(3) Alivecor Heart Monitor K142743

5.5 Device Description:

The non-invasive blood pressure measuring system HRVWatch-Mini Wrist Monitor is a smaller size variation of the HRVWatch Wrist Monitor (K123130) previously cleared by FDA in 2013. Identical to its larger-size predecessor in terms of device main functions, the Mini monitor measures blood pressures (BP) (systolic pressure SYS and diastolic pressure DIA) and heart rate (HR), using the oscillometric method commonly employed by electronic blood pressure meters. In addition, the device utilizes piezo-electrical sensors embedded in the cuff (wrist band) to obtain detailed radial arterial waveforms. The 5-minute continuous waveform recording allows the device to detect and report irregular heartbeats. Heart rate variability (HRV) parameters are also obtained by time- and frequency-domain statistical analyses of pulse peak-to-peak intervals. The main body of the device with its biosensors and electrical circuit boards has the full function of signal acquisition, analysis, and data storage. The testing by the device is controlled by a software programs (app) installed in a smart phone or tablet (the collateral device) via two-way blue-tooth communication. The display of the collateral device (phone or tablet) is used to show live test data plots during test, or post-test data reports and plots. Test data can be uploaded to

cloud using the collateral device's internet connectivity. HRVWatch-Mini Wrist Monitor is intended to provide only patient parameter measurements and associated rankings based upon established standard values, and is not intended to produce any clinical interpretation of those measurements or any kind of diagnosis.

5.6 Indications for Use:
Indications for Use: Non-invasive measurement of systolic pressure (SYS), diastolic pressure (DIA), heart rate (HR), heart rate variability (HRV), and irregular heartbeats (IrrHB) for professionals at office or patients at home. The device is not intended for ambulatory use. The device has not been tested and it is not intended for pediatric use. The device provides a HRV parameter which is only mathematical analysis and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

5.7 Comparison to **Predicate Device(s):**
The subject device HRVWatch-Mini wrist monitor is shown to be substantially equivalent to:
(1) HRVWatch Wrist Monitor K123130 (Prescription use; primary predicate device) for the measurement of BP, HR, HRV, and IrrHB
(2) Full Automatic (NIBP) Blood Pressure Monitor HL158UA K162338 (OTC use) for the measurement of BP, HR, and IrrHB
(3) Alivecor Heart Monitor K142743 (Prescription and OTC uses) for the measurement of IrrHB

In this submission, the subject device is shown to be substantially equivalent to the primary predicate device HRVWatch Wrist Monitor K123130 for the measurement of BP, HR, HRV, and IrrHB in the application of prescription use. HRVWatch-Mini is a size-reduced device designed from HRVWatch K123130, with identical key parts (the cuff, the BP pressure IC sensor, the PZT biosensor module, and the analytical firmware, etc.). HRVWatch K123130 connects to a Windows-based PC for data display, print, and upload, while the subject device is operated in connection with a smart phone or tablet (Android and iOS) via blue-tooth transmission.
The subject device is shown to be substantially equivalent to the predicate device "Full Automatic (NIBP) Blood Pressure Monitor HL158UA K162338" for the measurement of BP, HR, and IrrHB in the application of OTC use. K162338 does not measure HRV while the subject device does. However, the additional functionality of HRV measurement in the subject device does not pose any new safety concern.
The subject device is shown to be substantially equivalent to the predicate device "Alivecor Heart Monitor K142743" for the measurement of IrrHB in the application of prescription and OTC use. K142743 is designed for the recording, detection and data transmission of irregular heartbeat with a single-lead ECG, while the subject device performs the similar functions based upon the radial pulse waves.
From the documentation and test results included this submission, the subject device is substantially equivalent to the predicate devices list above for the measurement of BP, HR, HRV, and IrrHB in the application of prescription and over-the-counter (OTC) use.

5.8 Performance Summary (Bench and Clinical):
HRVWatch-Mini Wrist Monitor has been tested by both in-vitro (bench) and human clinical studies. The test results show that HRVWatch-Mini Wrist Monitor is in compliance with the following international standards, FDA Guidance documents, and literature articles:

(i) FDA Guidance "Noninvasive blood pressure meter submission guide" (March 10, 1997)
(ii) ANSI/AAMI SP10-1992 Electronic or Automatic Sphygmomanometers
(iii) ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
(iv) IEC 60601-1-2 Edition 4.0 2014-02 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
(v) ETSI EN 301 489-1 and ETSI EN300328 for blue-tooth emission compatibility
(vi) ISO 13485:2016 for Medical Devices
(vii) EC Declaration of Conformity (Medical Device Directive 93/42/EEC)
(viii) 1996 Heart Rate Variability publication in the journal of *Circulation* (*Circulation* **1996**, *93*, 1043-1065; regarded widely as the HRV International Standard)

5.9 Discussion of Clinical Test

(i) The submission subject device HRVWatch-Mini is a sized reduced model from the FDA cleared device HRVWatch Wrist Monitor K123130 (full size)
(ii) To confirm the design change, a small scale, open, random, sequential, and comparative study was conducted between HRVWatch-Mini and HRVWatch-Full-Size wrist monitors
(iii) A total of 10 subjects were recruited from company employees and family members for the human clinical study. Among the participants, 8 were men and 2 were women. Age range was from 18 to 86 years-old, height from 150 (4 foot 11 inch) to186 cm (6 foot 1 inch), and body weight from 45 (99.2 lb) to 75 Kg (165.3 lb). All participants lived in Taiwan and healthy.
(iv) Tests were conducted comparing two HRVWatch devices for measurement of BP, heart rate, heart rate variability (HRV), and irregular heartbeat (IrrHB)
(v) The clinical test results showed that HRVWatch-Mini was substantially equivalent to the predicate device HRVWatch-full-size for technical designs, functions, and data accuracy.

5.10 Conclusions:

After bench and clinical performance tests, HRVWatch-Mini was shown to be substantially equivalent to the predicate devices.