June 10, 2022

Wesper Inc.
Amir Reuveny
CEO
234 5th Ave
New York, New York 10001

Re: K213515
Trade/Device Name: WesperO2
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: May 11, 2022
Received: May 12, 2022

Dear Amir Reuveny:

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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthsia 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)*
K213515

Device Name
WesperO2

Indications for Use *(Describe)*
WesperO2 is a finger-worn pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It is intended for spot-check and/or continuous data collection, and not continuous monitoring. It can be used in sleep labs and home use.

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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Section 5. 510(k) Summary

WesperO2 Pulse Oximeter
Date Prepared: October 29, 2021

Name of Device and Sponsor Information

Device Name: WesperO2
Sponsor Name: Wesper Inc. (formerly Tatch Inc.)
Sponsor Address: 234 5th Ave., New York, USA, 10001
Phone: 917-841-4830
Contact Person: Amir Reuveny

Classification Name

Classification Name: Oximeter
Product Code: DQA
Regulation: 21 CFR 870.2700
Device Class: Class II

Predicate Device

Name: Oxiband (Checkme) O2 Pulse Oximeter
K-Number: K191088
Classification Name: Oximeter
Product Code: DQA
Regulation: 21 CFR 870.2700
Device Class: Class II
Sponsor Name: Shenzhen Viatom Technology Co., Ltd.

Indications for Use

WesperO2 is a finger-worn pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It is intended for spot-check and/or continuous data collection, and not continuous monitoring. It can be used in sleep labs and home use.

Device Description

WesperO2 (“the device”) is a pulse oximeter, meant to be worn on the finger of an adult patient over the age of 21. The device is intended for spot checking or continuous collection of functional oxygen saturation of arterial hemoglobin by way of sensing peripheral capillary perfusion (“SpO2”) and Pulse Rate. It is intended to be used in the patient’s home or in a sleep lab.

The device’s core technology is based on collecting reflected light from the intact skin of the patient’s finger to form Photoplethysmography (“PPG”) waveforms. These waveforms can then be used to extract a measurement of SpO2 and Pulse Rate.

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The sensing component is carried by an electronics assembly, which is comprised of a battery-powered Printed Circuit Board ("PCB"). The electronics assembly is housed inside of a soft, flexible casing, which encapsulates the entirety of the assembly, except for the actual optical front-end of the sensing component, which exposes an array, consisting of two LEDs and a photodiode. The entire assembly is referred to as "the WesperO2 probe."

The silicone housing has a "thimble-style" form factor, such that the patient can wear it on their fingertip, with the optical sensor pointed at the pad of their finger. The probe is then meant to create a snug, yet comfortable fit to ensure consistent positioning of the optical sensor throughout the usage period.

The probe has a Bluetooth interface through which it sends SpO2 and Pulse Rate measurements to a companion mobile application ("WesperO2 app"), which resides on the patient's mobile device. The application can both record the data and display it in real-time to the patient. Recordings are saved on the mobile device and can be shared later through the application with a healthcare provider over the internet.

Performance Data

Software

Wesper's software development life cycle is in accordance with the following standards:

- FDA Guidance: General Principles of Software Validation, January 2002
- FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005
- FDA Guidance: Off-The-Shelf Software Use in Medical Devices, September 2019
- IEC 62304:2006+AMD1:2015 CSV, Medical Device Software – Software Life-Cycle Processes
- ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices

Based on this process, Wesper has established it has a Moderate Level of Concern for its software used in the WesperO2 pulse oximeter. Therefore, Wesper has performed a detailed Risk Analysis and developed a Software Requirement Specification and Software Detailed Design which were verified and validated and shown to have full traceability back to all risk mitigations, which reduce the level of residual risk in the software to an acceptable level. Wesper has also performed Off-The-Shelf (OTS) Software validation.

In addition, Wesper has performed a full Cybersecurity Threat Analysis based on recommendations provided in FDA Guidance: "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," October 2014.

Electromagnetic Compatibility (EMC) and Electrical Safety

The following standards were met for EMC and Electrical Safety:

- IEC 60601-1:2005+AMD 2012, 3rd Ed. – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1, Part 11:2015 - General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

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- IEC 60601-1-2:2014 - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 80601-2-61:2017 - Particular requirements for basic safety and essential performance of pulse oximeter equipment [selected sections pertaining to safety]
- IEEE/ANSI C63.27-2017 - American National Standard for Evaluation of Wireless Coexistence

Biocompatibility

All skin-contacting materials in the WesperO2 probe have been tested to comply with ISO 10993-1 with conditions which meet Wesper's intended use of up to 24 hours at 37°C on intact skin.

Performance Testing – Bench

Validation of the Range of Heart Rate Measurement: Testing was performed to ensure that the WesperO2 pulse oximeter measures heart rate accurately over its targeted range. One heart rate measurement accuracy test was applied to three independently generated datasets. The test passed for every dataset. Based on these three successful tests, WesperO2 is validated for measuring heart rate across its target range of 30 to 230 BPM. This full range was not observed in clinical testing of the device. Therefore, bench testing was performed to supplement clinical testing in demonstrating the accuracy across the full target range.

Performance Testing – Animal

No animal testing was conducted for this 510(k) submission.

Performance Testing – Clinical

An SpO2 accuracy comparison was conducted as part of the final validation of the WesperO2 pulse oximeter. The study was conducted in accordance with the following standards:

- ISO 80601-2-61:2019, Medical electrical equipment - Particular requirements for basic safety and essential performance of pulse oximeter equipment
- FDA-2007-D-0205, Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff

The objective of the study was to validate the SpO2 accuracy of the WesperO2 pulse oximeter over the range of 70-100% SaO2 as compared to arterial blood sample CO-Oximetry. It was expected that the Accuracy Root Mean Square (ARMS) performance of the oximeter would meet the required specification of ARMS of 3.5% or less.

A secondary goal was to evaluate the Pulse Rate (PR) performance simultaneously collected over the SpO_2 range covered. The PR A_{RMS} performance of the WesperO2 pulse oximeter was expected to meet a specification of 3 Beats per Minute (BPM).

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Table 1: Summary of SpO2 Accuracy Results

Comparison to Reference CO-Oximetry (functional SaO_2)	SpO_2 Range	SpO_2 A_{RMS}	A_{RMS} Spec < 3.5%
WesperO2	70-100%	2.56 (N=223)	Pass

Table 2: Summary of Pulse Rate Accuracy Data

Comparison to Reference Oximeter Pulse Rate	Pulse Rate Range	Pulse Rate A_{RMS}	A_{RMS} Spec < 3BPM
WesperO2	59-122 BPM	2.2 (N=235)	Pass

The results of the study show that the WesperO2 pulse oximeter outperforms the ARMS specification of 3.5% for the range 70-100%. WesperO2 provides accurate PR values over the range 59-122 BPM, meeting a specification of 3 BPM.

The validated pulse rate range was extended beyond the limits of clinical observation to 30-230 BPM using bench testing.

Substantial Equivalence

Both devices use light absorption in the finger to measure SpO2 and Pulse Rate, and both use Red and Infra-Red as their working wavelength bands. The subject device uses reflected energy to measure absorption, while the predicate device uses transmitted energy to accomplish that. Both methods are well understood and accepted methodologies to accurately measure SpO2 and Pulse Rate.
Both devices have identical SpO2 and Pulse Rate ranges (70% - 100%, and 30BPM – 250BPM, respectively), with the subject device having a maximum resolution of 2BPM against the predicate's 1BPM resolution. This difference in resolutions is not clinically significant. The subject device has an overall Arms of 2.56%, while the predicate has an Arms of 1.88%. Both results are within the necessary acceptance criteria, making them clinically equivalent.

Both devices use silicone-based housings and are applied to the finger. The subject device is entirely contained in the fingertip unit and the predicate device attaches to a wrist-worn unit. Since both devices have biocompatible patient-contacting materials and similar form factors, they are functionally equivalent.

Both devices have capabilities to record, and display in real time, SpO2 and Pulse Rate. The subject device uses the companion mobile application via Bluetooth to achieve this, while the predicate has an on-board LCD display. The displayed measurements are the same both units perform the same function, and the subject device's software has been fully validated to meet the necessary functional requirements.

A substantial equivalence chart comparing the similarities and differences between WesperO2, and its predicate device is provided in Table 1. Differences in technology as described above do not raise new type questions of safety and effectiveness. Furthermore, clinical performance testing per ISO 80601-2-61:2019 and Pulse Oximeters - Premarket Notification Submissions [510(k)s] - Guidance for Industry and Food and Drug Administration

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Staff, March 4, 2013 has shown that WesperO2 successfully meets the accuracy criteria for Pulse Oximeters intended for marketing in the US.

Table 3: Substantial Equivalence Table

Characteristic	**Subject Device WesperO2**	**Predicate Device Oxiband (Checkme) O2 Pulse Oximeter (K191088)**	**Comparison**
Product Code	DQA	DQA	Same.
Class	II	II	Same.
Indications For Use	WesperO2 is a finger-worn pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It is intended for spot-check and/or continuous data collection, and not continuous monitoring. It can be used in sleep labs and home use.	The Oxiband Pulse Oximeter is a wrist pulse oximeter indicated for use in measuring, displaying, storing, and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It is intended for spot-check and/or continuous data collection, and not continuous monitoring. It can be used in sleep labs, long-term care, hospitals and home use.	Indications for use are similar between the two devices. The subject device is only indicated for sleep labs and home use which is a subset of the predicate's indications.
Intended application site	Finger	Finger	Same.
Continuous collection	Yes	Yes	Same.
Sensor form factor	Self-contained, wireless finger unit	Detachable, wired finger unit	Both devices target the finger, where the detachable design of the predicate does not affect the accuracy of the measurement.

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SpO2 measurement accuracy	70 - 100%: Arms = 2.56 70 - 80%: Arms = 3.6 80 - 90%: Arms = 2.05 90 - 100%: Arms = 1.84	70 - 100%: Arms = 1.88 70- 80%: ±3% 80- 90%: ±2% 90- 100%: ±2%	Both devices meet the necessary accuracy requirements for 70-100% and have similar error profiles decade-by-decade, therefore they have equivalent SpO2 measurement accuracies.
SpO2 display range	70 - 100%	0 - 100%	The predicate's extended display range has no practical significance, as both devices claim the same SpO2 range, which is the same as the subject's display range. The subject device's display range is within the range of the predicate device.
SpO2 resolution	1%	1%	Same.
Pulse Rate measurement range	30 - 230 BPM	30 - 250 BPM	Similar.
Pulse Rate accuracy	±3 BPM RMSE	±2 BPM or ± 2% (whichever is greater)	In the worst-case scenario, the two devices differ in 1 BPM on average, which is not clinically significant.
Pulse Rate resolution	2 BPM	1 BPM	1 BPM does not constitute a clinically significant difference.

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Display method	In-app via Bluetooth	On-unit OLED screen	Both devices will display the same type of live data. Both displays rely on software components to render the measurements, and Wesper performed software validation of the integrity and real-time response of the app display to demonstrate equivalence.
Wireless connectivity	Bluetooth	Bluetooth	Same.
Storage	Yes, on-probe and in-app	Yes, on-probe	Similar.
Contact duration	Up to 24h	Up to 24h	Same.

Conclusion

The information provided in this submission, in accordance with the requirements of 21 CFR 807 Subpart E, supports the conclusion that WesperO2 is substantially equivalent to the predicate device, the Oxiband (Checkme) O2 Pulse Oximeter.