March 9, 2023

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

Re: K221816
Trade/Device Name: Wesper Lab
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: February 8, 2023
Received: February 8, 2023

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

510(k) Number *(if known)*
K221816

Device Name
Wesper Lab

Indications for Use *(Describe)*
The Wesper Lab is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. Wesper Lab records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep apnea by trained personnel. Wesper Lab is intended to be used for adult sleep studies at home or clinical environment. The device does not actively monitor or diagnose the patient and does not issue any alarms.

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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WESPER

510(k) Summary

1. SUBMITTER

Company & Address:	234 5th Avenue New York, NY 10001 516-654-4166
Contact Person:	Amir Reuveny

Date Prepared: 11/18/2022

2. DEVICE

Name of Device:	Wesper Lab
Common or Usual Name:	Breathing frequency monitor.
Classification Name:	Breathing frequency monitor.
Regulation:	21 CFR 868.2375
Regulatory Class:	II
Product Code:	MNR

3. PREDICATE DEVICE

- Wesper Lab (K203343)

4. DEVICE DESCRIPTION

Wesper Lab (“the device”) is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. Wesper Lab records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep apnea by trained personnel.

The device consists of an abdominal patch, a thoracic patch and a mobile application. The patches are multi-use wearable, flexible, thin, and wireless, and are designed to record sleep data in adult patients. Both patches are the same and differ only in their anatomical designation, which is determined by the order in which the user applies them at test setup time. The flexible fabric allows the patch to contract and expand as the patient breathes and moves during sleep.

The mobile application (“the app”) resides on the patient’s personal mobile device, relaying sleep data wirelessly to a secure remote storage location (“the cloud”) for subsequent analysis by a healthcare professional. The app has 3 Bluetooth Low-Energy (BLE) ports, each of which receives multiple physiological channels from the patient.

The device’s BLE ports connect to the following:

1. Abdominal patch
2. Thoracic patch
3. Pulse oximeter

The patches collect multiple physiological parameters related to sleep to be used by a healthcare professional. Specifically, the patches measure sleep position, respiratory effort, and airflow / air pressure. The patches leverage accelerometry and optical sensing to provide these measurements.

Data from the patches is transmitted via BLE throughout the night to the app, which uploads the data to the cloud. A third BLE port on the app connects to an FDA cleared pulse oximeter, which provides heart rate and blood oxygen saturation measurements.

The data recorded by the patches is relayed to a remote secure storage, where it will be downloaded to a local PC. Then, Wesper staff will execute the Study Output Module (SOM) and save the data locally on the desktop computer. The data is then ready for interpretation by a healthcare provider.

5. INDICATIONS FOR USE

The Wesper Lab is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. Wesper Lab records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep apnea by trained personnel. Wesper Lab is intended to be used for adult sleep studies at home or clinical environment. The device does not actively monitor or diagnose the patient and does not issue any alarms.

6. COMPARISON OF INTENDED USE

Both the Wesper Lab and the predicate device have the same intended use, specifically, for the recording of physiological parameters from a sleeping patient.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is substantially equivalent to the predicate device (Wesper Lab, K203343). Both devices have the same intended use and similar indications, technological characteristics and principles of operation, with two design changes introduced in the subject device:

- A charging element was added to the patch's electronic assembly, which will receive energy from a corresponding charging pad ("Wesper Charger").
- The biocompatible adhesive layer at the bottom of the patch has been made replaceable, intended to be discarded after each nightly application. The adhesive material is identical to the one used in the predicate.

A substantial equivalence chart comparing the similarities and differences between the subject and the predicate device is provided in Table 1. Any minor differences in the technological characteristics do not raise different questions of safety or effectiveness.

Table 1: Substantial Equivalence Comparison of the Subject and Predicate Devices

	Wesper Lab (Subject) – K221816	***Wesper Lab (Predicate) – K203343***	***Similarities and Differences***
Classification regulation	21 CFR 868.2375		Same
Product code	MNR		Same
Intended Use	For the recording of physiological parameters from a sleeping patient.		Same
Indications for Use	The Wesper Lab is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. Wesper Lab records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep apnea by trained personnel. Wesper Lab is intended to be used for adult sleep studies at home or clinical environment. The device does not actively monitor or diagnose the patient and does not issue any alarms.	The Wesper Lab is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. Wesper Lab records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep apnea by trained personnel. Wesper Lab is intended to be used for adult sleep studies at home or clinical environment. The body-worn component of the system is single-use, to be discarded after its dedicated nightly application. The device does not monitor or diagnose the patient and does not issue any alarms.	Similar The indications for use for the subject device have been modified from the predicate to remove references to single use limitations. This change does not raise any different questions of safety or effectiveness.
Intended environment(s)	Home or clinical environment		Same

Patient population	Adults		Same
Rx or OTC	Rx		Same
Device Type	Wearable Sensor		Same
Main anatomical Site	Torso		Same
Airflow	Indirect measurement using respiratory effort signals.		Same
Respiratory Efforts	Thoracic and abdominal effort based on optical sensor.		Same
Body Position	Solid State Accelerometer		Same
Body adherence method	Biocompatible double-sided silicone-based adhesive, separable	Biocompatible double-sided silicone-based adhesive, non-separable	Similar
Display type	Visual display including LEDs and device specific visual indicators.		Same
Power source	Internally powered using li-ion battery		Same
Charging	Multiple times in patient's home or clinical environment	Once at manufacturing	Similar The difference in the charging mechanism has been tested using IEC 60601 and IEC 62133 to show that there is no change in the safety, EMC or usability risk profile of the device.
Data storage	Internal memory and secured cloud storage		Same
Communication interface	Bluetooth low energy (BLE)		Same
Access to recorded data	Output file available to healthcare provider for review		Same

Device dimensions	3.8 L x 2.1 W x 0.23 D (inches, max)		Same
Biocompatibility	Biocompatible in accordance with ISO 10993		Same
Signal Recorded Channels	1. Thoracic effort 2. Abdominal effort 3. Body position 4. Airflow 5. Pressure		Same
Internal memory	Flash memory card. Recording time 40 hours.		Same
Pulse oximeter	Coupled with an authorized FDA-cleared pulse oximeter to measure pulse-rate and SpO2.		Same
Sterility	Non-sterile		Same
Electrical safety	IEC 60601, IEC 62133	IEC 60601	Similar The predicate device's test standards are included in the subject device's safety test profile.

8. PERFORMANCE DATA

Wesper has performed bench testing on its device battery to establish its reusability lifetime and has provided cleaning instructions to the operator to apply between uses.

In addition, Wesper conducted comprehensive performance testing according to the following standards and guidelines:

8.1. Electrical Safety / EMC

- IEC 60601 – Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – requirements and tests
- IEC 60601 - Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
- IEEE/ANSI C63.27 – Evaluation of wireless coexistence
- IEC 60529 ED. 2.2 B:2013 - Degrees of protection provided by enclosures (IP Code).
- IEC 62133 – Secondary cells containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems (2017)

Wesper Lab met all acceptance criteria.

8.2. Usability / Human Factors

Wesper Lab has been assessed to have no critical tasks as established by a Use-Related Risk Analysis, confirmed by a usability study. This assessment was conducted in accordance with IEC 62366 - Medical devices — Part 1: Application of usability engineering to medical devices and FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices”, issued February 2016.

CONCLUSION

The Wesper Lab (subject) and Wesper Lab (predicate, K203343) have the same intended use and similar indications, technological characteristics, and principles of operation. The technological differences between the subject and the predicate device, as described above, do not present different questions of safety or effectiveness. The data provided demonstrates that Wesper Lab is substantially equivalent to its predicate.