December 21, 2021

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

Re: K203343
Trade/Device Name: Wesper Lab
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: November 19, 2021
Received: November 23, 2021

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, 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

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)*

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 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.

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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510(k) Summary

1. SUBMITTER

Company & Address: Wesper Inc.
234 5th Avenue
New York, NY 10001
516-654-4166

Contact Person: Amir Reuveny

Date Prepared: November 11, 2020

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

- Natus Medical Embletta MPR PG (K122516) (Predicate Device)
- Compumedics Summit IP (K040194) (Reference Device)
- Dymedix Reusable Respiratory Effort Belt Model 6015 (K040605) (Reference Device)

Neither the predicate nor reference devices have been subject to a design-related recall.

4. DEVICE DESCRIPTION

Wesper Lab (“the device”) is indicated as 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 device consists of an abdominal patch, a thoracic patch and a mobile application. The patches are single-use wearable, flexible, thin, and wireless, and are designed to record sleep data in adult patients. Both patches are identical and differ only in their anatomical designation at test setup time. The flexible fabric allows the patch to retract 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 patches collect multiple physiological parameters related to sleep to be used by a healthcare professional. Specifically, the patches measure sleep position, respiratory effort, and Wesper-Sum- Flow / Wesper-Sum-Pressure.

Data from the patches is transmitted via Bluetooth low energy (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 pulse 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 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.

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

Recording of multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters is the technical principle for both the subject and predicate devices. The displayed data assists in the identification of sleep apnea by trained personnel. The subject and the predicate device (K122516) are based on the following similar technological elements:

- Input from respiratory effort sensors
- Coupled with an FDA- cleared pulse oximeter
    - Currently compatible with the Nonin WristOx Model 3150 BLE
- Body position output
- Data storage
- Study access via file

The following technological differences exist between the subject and predicate devices:

- Both devices are placed around or on the torso area and measure respiratory effort. The predicate device records respiratory effort measurements from compatible flexible belts using Respiratory Inductance Plethysmography (RIP) or Polyvinylidene Fluoride (PVDF) sensors, while Wesper Lab records respiratory effort measurements from flexible adhesive patches.

- The Wesper Lab and predicate Embletta MPR PG are similar as they measure the flow of air and its pressure. However, they differ in that the Wesper Lab does not produce a direct measurement of airflow using a nasal cannula to sense physiological flow of air as the Embletta MPR PG does.
- The reference devices demonstrate that there are other legally marketed Class II devices that utilize an indirect assessment of airflow (K040194) and a localized measurement of respiratory effort (K040605) and that these differences between the subject and the predicate device do not raise new questions of safety and effectiveness.
- Both the subject and predicate devices record data on the device and then transmit the data to another location. The subject device transmits the data wirelessly to a mobile phone and cloud storage, whereas the predicate device uses wireless transmission to a proprietary relay.

Below is a table containing a comprehensive comparison of the subject and predicate devices:

Device & Predicate Device(s):	Wesper Lab (K203343)	Embletta MPR PG (K122516)	Similarities and Differences
Classification regulation	21 CFR 868.2375	21 CFR 868.2375	Same
Product code	MNR	MNR	Same
Intended Use	For the recording of physiological parameters from a sleeping patient.	For the recording of physiological parameters from a sleeping patient.	Same
Intended environment	Home or clinical environment	Home or clinical environment	Same
Patient population	Adults	Adults and pediatric	Similar; substantially equivalent
Device Type	Wearable Sensor	Wearable Sensor	Same
Main anatomical Site	Thorax, Abdomen, Finger	Head, Thorax, Abdomen, Finger	Similar; substantially equivalent
Airflow	Indirect measurement using respiratory effort signals.	Direct measurement using pressure transducers and thermistors.	Similar; substantially equivalent
Respiratory Efforts	Thoracic and abdominal effort based on	Thoracic and abdominal effort based on	Similar; substantially equivalent

	optical sensor.	RIP / PVDF sensors.	
Body Position	Solid State Accelerometer	Solid State Accelerometer	Same
Display type	Visual display including LEDs and device specific visual indicators.	Visual display including LEDs and device specific visual indicators.	Similar; substantially equivalent
Power source	Internally powered using li-ion battery	2 x AA batteries, standard alkaline or rechargeable	Similar; substantially equivalent
Data storage	Internal memory and secured cloud storage	Internal memory and secured cloud storage	Same
Communication interface	Bluetooth low energy (BLE)	Bluetooth low energy (BLE) and USB	Similar; substantially equivalent
Access to recorded data	Output file downloaded to a dedicated PC.	Output file downloaded to a dedicated PC.	Same
Device dimensions	3.8 L x 2.1 W x 0.23 D	3.9 L x 2.8 W x 0.4 D	Similar; substantially equivalent
Biocompatibility	Biocompatible in accordance with ISO 10993	Biocompatible in accordance with ISO 10993	Same
Signal Recorded Channels	1. Thoracic effort 2. Abdominal effort 3. Body position 4. Airflow 5. Pressure	1. Gravity 2. Thoracic effort 3. Abdominal effort 4. Body position 5. Airflow 6. Pressure 7. Sound 8. Bipolar ExG	Similar; substantially equivalent
Pulse oximeter	Coupled with an authorized FDA-cleared pulse oximeter	Coupled with an authorized FDA-cleared pulse oximeter	Same

	to measure pulse-rate and SpO2.	to measure pulse-rate and SpO2.	
Sterility	Non-sterile	Non-sterile	Same
Electrical safety	IEC 60601	IEC 60601	Same

8. PERFORMANCE DATA

8.1 Transit Testing

To show the packaging solution's safety in transit, Wesper tested it against ISTA 3A – Packaged- Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard, small, flat or elongated). This procedure simulates the physical process of shipping the product through normal small parcel distribution channels, by running it through a series of steps, such as atmospheric conditioning, vibration, etc. Wesper Lab met all acceptance criteria.

8.2. Biocompatibility Testing

The biocompatibility evaluation for the Wesper Lab was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Wesper Lab is considered tissue contacting for less than 24 hours. The patient contacting materials of the Wesper Lab are biocompatible.

8.3 Software

Software development and testing has been performed for Wesper Lab in accordance with IEC 62304:2006+AMD1:2015 CSV, Medical Device Software – Software Life-Cycle Processes, and 'General Principles of Software Validation - Final Guidance for Industry and FDA Staff'. Additionally, cyber security risks have been assessed in accordance with the FDA Guidance 'Content of Premarket Submissions for Management of Cybersecurity in Medical Devices'. The software for this device is considered as a "moderate" level of concern, a malfunction or a latent design flaw in the software device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury.

8.4. Electrical Safety / EMC

The Wesper Lab was tested in accordance with IEC 60601 – Medical Electrical Equipment and IEC 60529 ED. 2.2 B:2013 - Degrees of protection provided by enclosures (IP Code). Wesper Lab met all acceptance criteria.

8.5. Bench Testing

Wesper's bench testing demonstrated substantial equivalence to the predicate for body position measurement. Acceptance criteria required that the devices agree to within a 45° interval for the entire range of degrees tested. The Wesper Lab met the acceptance criteria. Wesper conducted a bench test with a simulated breathing apparatus, comparing its respiratory effort sensors with the predicate's RIP technology over a range of breath frequencies amplitudes, and

perturbations (ex. BMI, body hair). The test showed Wesper Lab met or exceeded the predicate's performance in detecting clinically significant breathing events. Wesper conducted integration tests, to show the integrity of its interface with the Nonin WristOx.

8.4. Clinical Testing

Wesper has conducted a prospective, multi-center clinical study for Wesper Lab to demonstrate equivalence to the gold standard – in-lab, polysomnographic (PSG) tests. Wesper Lab was applied to 45 patients undergoing an attended PSG study, with both systems recording their respective signals simultaneously from the patient. Study results showed a correlation between Wesper Lab and PSG AHI of 95.1%, with a onesided lower confidence interval of 91%. The slope and intercept were not statistically different from 1 and 0, respectively. No Adverse Events or Serious Adverse Events were reported. The study had a wide, well-distributed range of age (22-76 years), race (white, black and others), BMI (19.6-56.1) and skin tone (Fitzpatrick skin tone type II-VI), as well as a balanced mix of gender (60% male).

9. CONCLUSION

The Wesper Lab and Embletta MPR PG have the same intended use and similar indications, technological characteristics and principles of operation. The technological differences between the Wesper Lab and the predicate device, as described above, do not present different questions of safety or effectiveness. Where differences exist, reference devices have been utilized that further demonstrate that there are no different questions of safety and effectiveness for the Wesper Lab.

The data provided in this 510(k) Premarket Notification support substantial equivalence of the Wesper Lab and Embletta MPR PG.