February 6, 2021

MultiSensor Diagnostics (dba Aidar Health)
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K201635
Trade/Device Name: MouthLab Vital Signs Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DPS, FLL, BZQ, BZH, DPS
Dated: December 23, 2020
Received: December 28, 2020

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,

for 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)*
K201635

Device Name
MouthLab Vital Signs Monitoring System

Indications for Use *(Describe)*
The MouthLab Vital Signs Monitoring System is a hand-held, wireless device intended to record, transfer, store and display single lead electrocardiography (ECG), heart rate (HR), heart rate variability (HRV), functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), respiration rate (RR), respiration pattern (RP), oral temperature (TEMP) and basic lung function measurements: peak expiratory flow (PEF) and forced expiratory volume in one second (FEV1).

This system is for spot checking and does not have continuous monitoring capability or any alarm features. The device comes in contact with the user for approximately 60 seconds at each use and the captured medical parameters shall be displayed on a mobile application.

It is intended for use by adults in the home environment and in healthcare facilities. This system makes no specific diagnosis. Respiration rate is not intended for adults with underlying or suspected medical conditions. The device is for single user use.

It is intended for use with users who are well perfused and during no motion condition. Users with implanted pacemakers and/or implanted cardioverter-defibrillators (ICDs) are not recommended to use the device.

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

Device Common Name:	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Device Trade Name:	MouthLab™ Vital Signs Monitoring System
Applicant	Multisensor Diagnostics, LLC. (DBA Aidar Health) 3402 Birch Hollow Rd, Pikesville, MD 21208 Phone: (443) 875-6456 Website: www.aidar.com
Contact:	Sathya Elumalai Founder & Chief Executive Officer selumalai@aidar.com
Representative/ Consultant:	Allison C. Komiyama, Ph.D., R.A.C. AcKnowledge Regulatory Strategies, LLC Telephone: +1(619) 458-9547 Email: akomiyama@acknowledge-rs.com Website: www.AcKnowledge-RS.com
Date Prepared:	February 4, 2021
Classification Regulation:	Class II
Classification Name:	870.2300: Cardiac monitor (including cardiotachometer and rate alarm)
Panel:	Cardiovascular
Primary Product Code:	MWI
Secondary Product Codes:	DQA, DPS, FLL, BZQ, DXN, BZH
Predicate Devices:	Primary: CheckMe Pro Health Monitor (K150869) Secondary: Connex Vital Signs 6000 Monitor (K171621) Wing Smart FEV1 and Peak Flow Meter (K152276)
Reference Devices:	• Masimo Acoustic Respiration Sensor (K120984) • ReadMyHeart - Model RMHI3.0 (K050620) • Peak.me (K180487)

1. INDICATIONS FOR USE:

The MouthLab Vital Signs Monitoring System is a hand-held, wireless device intended to record, transfer, store and display single lead electrocardiography (ECG), heart rate (HR), heart rate variability (HRV), functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), respiration rate (RR), respiration pattern (RP), oral temperature (TEMP) and basic lung function measurements: peak expiratory flow (PEF) and forced expiratory volume in one second (FEV1).

This system is for spot checking and does not have continuous monitoring capability or any alarm features. The device comes in contact with the user for approximately 60 seconds at each use and the captured medical parameters shall be displayed on a mobile application.

It is intended for use by adults in the home environment and in healthcare facilities. This system makes no specific diagnosis. Respiration rate is not intended for adults with underlying or suspected medical conditions. The device is for single user use.

It is intended for use with users who are well perfused and during no motion condition. Users with implanted pacemakers and/or implanted cardioverter-defibrillators (ICDs) are not recommended to use the device.

2. DEVICE DESCRIPTION:

The MouthLab Vital Signs Monitoring System is a non-invasive, battery-powered, hand-held, wireless, personalized single-user, vital sign measuring apparatus. The device is intended to intermittently monitor the user vitals through the use of an integrated SpO_2 sensor, ECG electrodes, microphones and thermistor, which measures the users' functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), oral temperature (TEMP), ECG, heart rate (HR) and heart rate variability (HRV). The users' respiration rate (RR) measurements, respiration pattern (RP) and the basic lung functions (FEV1 and PEF) measurements are obtained are obtained through the acoustic measurement of air turbulence. The vital signs data are transferred to the Aidar Cloud™ Application via a cellular network for processing and storage. This processed data is then displayed on the Aidar Care™ Mobile Application.

3. BIOCOMPATIBILITY:

The MouthLab Vital Signs Monitoring System is a surface device that includes components that have prolonged contact duration (> 24h and less than 30 days) with the

user's mucosal membrane and intact skin. Testing was performed in accordance with ISO 10993-1.

4. PERFORMANCE DATA:

4.1. Bench Testing:

The following bench testing was provided to support the substantial equivalence of the MouthLab Vital Signs Monitoring System:

- **ECG and Heart Rate Measurements**: To validate the ability of the MouthLab Vital Signs Monitoring System to capture ECG waveforms and heart rate measurements, bench testing as per IEC 60601-2-27:2012 was conducted.

- **Pulse Rate Measurements**: To validate the ability of the MouthLab Vital Signs Monitoring System to capture pulse rate measurements, bench agreement testing as per ISO 80601-2-61:2017 was conducted.

- **Temperature Measurements**: To validate the ability of the MouthLab Vital Signs Monitoring System to calculate temperature measurements, a bench agreement study was conducted, as per ISO 80601-2-56:2017.

- **Peak Flow Measurements**: To validate the ability of the MouthLab Vital Signs Monitoring System to measure the basic lung functions (FEV1 and PEF), bench testing according to the ATS Standardization of Spirometry, 2005 Update was conducted.

4.2. Clinical Testing:

The following clinical testing was provided to support the substantial equivalence of the MouthLab Vital Signs Monitoring System:

- **SpO_2 Measurements**: To validate the ability of the MouthLab Vital Signs Monitoring System to make pulse oximetry measurements, a clinical agreement study as per ISO 80601-2-61:2017 was conducted. MouthLab SpO_2 measurements were validated in a controlled desaturation study with adults and compared to reference co-oximeter analysis of arterial blood gas.

  Respiration Rate Measurements: To validate the ability of the MouthLab Vital Signs Monitoring System to calculate respiration rate, a clinical agreement study was conducted with 20 healthy adults and MouthLab respiration rate measurements were compared against a clinician's manually scored capnography ($EtCO_2$) waveforms.

5. SOFTWARE DOCUMENTATION:

Software documentation for a Moderate Level of Concern device was provided in support of the MouthLab Vital Signs Monitoring System as recommended by FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,* dated May 11, 2005 and IEC 62304:2006 + A1:2015.

6. ELECTRICAL SAFETY TESTING:

The MouthLab Vital Signs Monitoring System was found to be compliant with the following standards:

- IEC 60601-1:2005 + A1:2012
- IEC 60601-1-6:2010 + A1:2013
- IEC 60601-1-11:2015

7. ELECTROMAGNETIC COMPATIBILITY TESTING:

The MouthLab Vital Signs Monitoring System was found to be compliant with IEC 60601-1-2:2014 standard.

8. HUMAN FACTORS/USABILITY TESTING:

Human factors/usability testing was conducted to evaluate the ability of lay people to read and understand the MouthLab Vital Signs Monitoring System instructions for use, and subsequently simulate normal use of the MouthLab Vital Signs Monitoring System with limited training. The MouthLab Vital Signs Monitoring System was also tested as per IEC 60601-1-11:2015, for suitability of the system in a home environment.

9. SUBSTANTIAL EQUIVALENCE DISCUSSION:

The MouthLab Vital Signs Monitoring System is substantially equivalent to the predicate devices based on the information summarized here.

The subject device has the same intended use and similar technological characteristics as the predicate devices cleared in K150869, K171621, and K152276. The primary predicate, CheckMe Pro Health Monitor (K150869) is also a handheld device for monitoring physiological parameters in the home or healthcare environment. The subject device has seven primary medical device functions and each of them have been compared to predicate devices. There are no differences in the technological characteristics for SpO_2, Pulse Rate, Heart Rate, ECG, Temperature, Respiration Rate, Respiration Pattern, PEF and FEV1. The subject device also measures the heart rate variability (HRV) in R-R interval, which is a mathematical analysis of the variation in the

heart rate and is not intended to produce any interpretation of those measurements or be used for any kind of diagnosis.

The similar indications for use, technological characteristics, and performance characteristics for the proposed MouthLab Vital Signs Monitoring System are assessed to be substantially equivalent to the predicate devices. A comparison of the technological characteristics between the subject device and the predicate devices is provided in the tables below.

Table 1: Technological Comparison – MouthLab System vs CheckMe Pro

	Subject Device	Primary Predicate	Substantial Equivalence to Predicate Device
510(k) Number	K201635	K150869	NA
Applicant	Multisensor Diagnostics, LLC	Viatom Technology Co. Ltd.	NA
Device Name	MouthLab Vital Signs Monitoring System	CheckMe Pro Health Monitor	NA
Classification Regulation	870.2300 - Physiological Patient Monitor	870.2300 – Physiological Patient Monitor	Same
Device Class	Class II	Class II	Same
Physiological Parameters Monitored	ECG, HR, HRV, SpO2, PR, RR, RP, TEMP, PEF, FEV1	ECG, HR, SpO2, PR, TEMP	Similar
Location	Home and Healthcare facilities	Home and Hospital	Same
Rx or OTC	Rx	Rx	Same
Power Supply	2000mAh rechargeable lithium-polymer battery	560mAh rechargeable lithium-ion polymer battery	Similar
User Population	Adults	Adults and Pediatric	Subject device only supports adult users
Alarm	No Alarms	No Alarms	Same
Data Collection Memory	Minimum of 10,000 measurements storage	100 measurements storage	Similar

	Subject Device	**Primary Predicate**		**Substantial Equivalence to Predicate Device**
Operating Modes	Spot-Check	Continuous Recording and Spot-Check		Subject device only supports spot-check
Comparison of ECG and Heart Rate Measurements				
Measured ECG Parameters	ECG Waveform, Heart Rate (HR), Heart Rate Variability (HRV)	ECG Waveform, Heart Rate (HR)		Similar
ECG Rhythm Classification	Not Included	Not Included		Same
ECG Lead Type	Single Lead, 2 Contacts	External ECG Cable and Electrodes	Integrated Single Lead ECG Electrodes	Similar
Input Impedance	> 2.5MΩ	> 10MΩ	> 10MΩ	Conforms to IEC 60601-2-27 impedance requirements
Input Dynamic Range	± 2mV	± 3mV	± 3mV	Subject device supports this range
Bandwidth	0.5 – 50 Hz	0.05 – 40 Hz	0.67 - 40 Hz	Similar
A/D Conversion	24 bit	16 bit		Similar
Sampling Rate	1000 Hz	500 Hz		Similar
Measurement Time	≤ 60 seconds	30 seconds		Similar
Display	Mobile Application	400*240 Dot-matrix LCD Display		Subject device only supports mobile application.
Input	Dry Conductive Electrodes	Dry Conductive Electrodes and/or External Auxiliary Electrodes		Similar
Heart Rate (HR) Range	30 – 200 bpm	30 – 250 bpm		Conforms to the requirements of the IEC 60601-2-27 heart rate measurements

	Subject Device	Primary Predicate	Substantial Equivalence to Predicate Device
Heart Rate (HR) Accuracy	± 2 bpm or ± 2%, whichever is larger	± 2 bpm or ± 2%, whichever is larger	Same
Comparison of Blood Oxygen Saturation (SpO_2) Measurements			
Display Data	SpO_2, Pulse Rate (PR)	SpO_2, Pulse Rate (PR)	Same
Mode	Spot-Check	Continuous Recording and Spot-Check	Subject device only supports spot-check
Sensor Types	Integrated	Integrated and External	Subject device only supports integrated sensors
SpO_2 Range	70 – 100%	70 – 100%	Same
SpO_2 Accuracy	± 3%	Integrated: ± 3%	Same
SpO_2 Resolution	1%	1%	Same
Pulse Rate (PR) Range	30 – 250 ppm	30 – 250 ppm	Same
Pulse Rate (PR) Accuracy	± 2 ppm or ± 2%, whichever is larger	± 2 ppm or ± 2%, whichever is larger	Same
Pulse Rate (PR) Resolution	1 ppm	1 ppm	Same

Table 2: Technological Comparison – MouthLab System vs Connex Monitor

Comparison of Respiration Rate Measurement			
	Subject Device	**Secondary Predicate**	**Substantial Equivalence to Predicate Device**
510(k) Number	K201635	K171621	NA
Applicant	Multisensor Diagnostics, LLC	Welch Allyn, Inc	NA
Device Name	MouthLab Vital Signs Monitoring System	Connex Vital Signs Monitor	NA
Classification Regulation	870.2300 -	870.2300 –	Same

	Subject Device	Secondary Predicate	Substantial Equivalence to Predicate Device
	Physiological Patient Monitor	Physiological Patient Monitor	
Device Class	Class II	Class II	Same
Location	Home and Healthcare Facilities	Hospital	Similar
Measurement Techniques	Acoustic Measurements	Acoustic Measurements	Same
Display Range	6 – 50 breaths/min	4 – 70 breaths/min	Subject device supports this range
Measurement Range	6 – 50 breaths/min	4 – 70 breaths/min	Subject device supports this range
Respiration Rate (RR) Accuracy	± 2 breaths/min	± 1 breath/min	Subject device supports this accuracy
Comparison of Temperature Measurement			
Measurement Technique	Thermo-resistive Sensor	Thermo-resistive Sensor	Same
Measurement Site	Oral	Oral, Axillary, Rectal	Subject device only supports oral measurements
Mode	Direct Mode	Direct or Predictive Mode	Subject device only supports direct mode
Unit	ºF or ºC	ºF or ºC	Same
Measuring Range	93.2ºF – 109.4ºF (34ºC – 43.0ºC)	80ºF – 110ºF (26.7ºC – 43.3ºC)	Conforms to the ISO standard requirements
Accuracy	± 0.6 ºF (± 0.3ºC)	± 0.2ºF (± 0.1ºC)	Conforms to the ISO standard requirements

Table 3: Technological Comparison – MouthLab System vs Wing

Comparison of Lung Function Measurements			
	Subject Device	**Secondary Predicate**	**Substantial Equivalence**
510(k) Number	K201635	K152276	NA

	Subject Device	Secondary Predicate	Substantial Equivalence
Applicant	Multisensor Diagnostics, LLC	Sparo Labs	NA
Device Name	MouthLab Vital Signs Monitoring System	Wing Smart FEV1 and Peak Flow Meter	NA
Classification Regulation	870.1860 – Peak Flow Meter for Spirometry	870.1860 – Peak Flow Meter for Spirometry	Same
Device Class	Class II	Class II	Same
Physiological Parameters Monitored	FEV1, PEF	FEV1, PEF	Same
Location	Home and Hospital	Home	Similar
User Interface	Mobile Application	Mobile Application	Same
Rx or OTC	Rx	OTC	Subject device is only applicable for prescription use based on other parameters it measures
Use Population	Adults	Adults and pediatric users above 5 years of age	Subject device is for adult users
Operating Modes	Spot-Check	Spot-Check	Same
Measurement Technique	Acoustic Measurement using Microphones	Acoustic Measurement using Microphones	Same
Peak Expiratory Flow (PEF) Range	2 – 15 L/s	50 – 900 L/min	Subject device supports this range
Peak Expiratory Flow (PEF) Accuracy	± 0.33 L/s or 10%, whichever is larger	±20 L/min or 10%, whichever is larger	Same
PEF Resolution	0.01 L/s	1 L/min	Same
Forced Expiratory Volume (FEV1) Range	1.00 – 7.50 L	0.01 – 9.99 L	Subject device supports this range
Forced Expiratory Volume (FEV1) Accuracy	± 0.1 L or 5%, whichever is larger	± 0.1 L or 5%, whichever is larger	Same

	Subject Device	Secondary Predicate	Substantial Equivalence
FEV1 Resolution	0.01 L	0.01 L	Same

10. CONCLUSION:

Based on the information provided in this 510(k) premarket notification, the MouthLab Vital Signs Monitoring System is considered to be substantially equivalent (safe and effective) to its predicate devices: CheckMe Pro Health Monitor (K150869), the Welch Allyn Monitor (K171621), and Wing Smart FEV1 and Peak Flow Meter (K152276). The MouthLab Vital Signs Monitoring System has the same intended uses, similar indications, technological characteristics and principles of operation as its predicate devices. Through the performance and clinical testing conducted as mentioned herein, the minor technological differences between MouthLab Vital Signs Monitoring System and its predicate devices raise no new issues of safety and effectiveness. Hence, the MouthLab Vital Signs Monitoring System is substantially equivalent to its predicate devices.