June 4, 2024

Snap Diagnostics, LLC
℅ Tom Renner
Regulatory Consultant
Vision28
915 SW Rimrock Way
Suite 201-402
Redmond, Oregon 97756

Re: K240100
Trade/Device Name: SAM Model 9-10000
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: April 26, 2024
Received: April 30, 2024

Dear Tom Renner:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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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)*
K240100

Device Name
SAM Model 9-10000

Indications for Use *(Describe)*
The SNAP Diagnostics SAM Model 9-10000 device is intended to record airflow, breathing effort and body position, and is indicated for use as an aid for diagnostic evaluation of patients for apnea and snoring.

The SNAP Diagnostics SAM Model 9-10000 is not intended as a substitute for full polysomnography when additional parameters such as sleep stages or EEG activity are required.

The target population consists of patients who are suspected of apnea and/or complain about snoring. The majority of the test procedures will take place at the patient's home, although some may take place in a sleep laboratory. Both pediatric and adult patients may be tested.

Use of this device must be under the direct supervision of a qualified adult (parent or guardian) or health care practitioner trained in the use of the Snap Diagnostics SAM Model 9-10000 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.

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K240100 SAM Model 9-10000
Traditional 510(k) Summary

Contact Details

Applicant Name:	Snap Diagnostics, LLC
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Correspondent Contact:	Tom Renner
Correspondent Contact Phone:	541-359-5939
Correspondent Contact Email:	tom@vision28.com

Device Information

Device Trade Name:	SAM (Model 9-10000)
Common Name:	Breathing frequency monitor
Classification Name:	Ventilatory Effort Recorder
Regulation Number:	868.2375
Product Code:	MNR

Legally Marketed Predicate Device

Predicate #:	K110064
Predicate Trade Name:	Snap Model 8
Product Code:	MNR

Intended Use/Indications for Use

The SNAP Diagnostics SAM Model 9-10000 device is intended to record airflow, breathing effort and body position, and is indicated for use as an aid for diagnostic evaluation of patients for apnea and snoring.

The SNAP Diagnostics SAM Model 9-10000 is not intended as a substitute for full polysomnography when additional parameters such as sleep stages or EEG activity are required.

The target population consists of patients who are suspected of apnea and/or complain about snoring. The majority of the test procedures will take place at the patient's home, although some may take place in a sleep laboratory. Both pediatric and adult patients may be tested.

Use of this device must be under the direct supervision of a qualified adult (parent or guardian) or health care practitioner trained in the use of the Snap Diagnostics SAM Model 9-10000 device.

Device Description Summary

The Snap Diagnostics SAM Model 9-10000 is an upgraded version of the Snap Diagnostics Model 8 (K110064, the predicate device) where the only area of change is the data logger component of the Model 8 sleep apnea home sleep test (HST) and recording system. The SAM Model 9-10000 is meant to be used with previously-cleared components of the predicate device including Snap Model 8 accessories and Snap Model 8 analysis software.

The Snap Diagnostics SAM Model 9-10000 differs from the K110064 predicate in the implementation of built in piezo electric effort and body position sensors rather than using external sensors, incorporation of the device electronics into the belt-worn effort sensor enclosure, and support for external wrist worn oximeters (Wellue CheckMe Oximeter cleared under K191088 and Nonin 3150 Oximeter cleared under K102350).

The Snap Diagnostics SAM Model 9-10000 interfaces with the K110064 predicate analysis software only by way of exporting files using the USB port, and this occurs at Snap Diagnostics or a lab location. The SAM Model 9-10000 cannot transfer files over the internet. These files are identical in format to the files output by the predicate data logger. The K110064 predicate analysis software is unchanged and is not the subject of this 510(k).

Just like the Snap Diagnostics Model 8 predicate device, the Snap Diagnostics SAM Model 9-10000 is designed to be used in the patient's home. A SAM Model 9-10000 with a fully charged battery is delivered to the patient along with accessories. The patient uses the data logger for one or more overnight recordings, then returns the device and accessories to Snap Diagnostics or the lab. A technician retrieves the data from the SAM Model 9-10000 using the USB port. The previously-cleared analysis software (K110064) is then used by a supervising technician to review the data and generate a home sleep test (HST) report. This HST report is sent by Snap Diagnostics to the patient's clinical team, who interpret the HST in the context of other relevant clinical data. Just like for the predicate device, Snap Diagnostics or a lab wipes the SAM Model 9-10000 of all data, cleans, inspects, and recharges it, and then provides the SAM Model 9-10000 to the next patient for use.

The Snap Diagnostics SAM Model 9-10000 is capable of logging the heart rate and blood oxygenation data from external wrist worn oximeters (Wellue CheckMe Oximeter cleared under K191088 and Nonin 3150 Oximeter cleared under K102350), but does not itself measure or otherwise manipulate those data.

Just like the predicate, the Snap Diagnostics SAM Model 9-10000 itself measures sound/airflow, respiratory effort, and acceleration/position.

The Snap Diagnostics SAM Model 9-10000 data logger does not perform sleep scoring or any other diagnostic, analysis, visualization, or data transform function, nor does the device have the capacity for alarms or the triggering of actions or therapies.

Comparisons with the Predicate

I. Indication for Use

The two systems are the same in their regulatory parameters including indications for use, intended population, regulatory class, classification name and product code.

II. Regulatory Parameters

	Snap SAM Model 9-10000	Snap Model 8 (K110064)	Differences
Indications for use	The **SNAP Diagnostics SAM Model 9-10000** device is intended to record airflow, breathing effort and body position and is indicated for use as an aid for diagnostic evaluation of patients for apnea and snoring. The **SNAP Diagnostics SAM Model 9-10000** is not intended as a substitute for full polysomnography when additional parameters such as sleep stages or EEG activity are required. The target population consists of patients who are suspected of apnea and/or complain about snoring. The majority of the test procedures will take place at the patient's home, although some may take place in a sleep laboratory. Both pediatric and adult patients may be tested. Use of this device must be under the direct supervision of a qualified adult (parent or guardian) or health care practitioner trained in the use of the **Snap Diagnostics SAM**	The **Snap Model 8** device is indicated for use in the diagnostic evaluation of patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring. The **SNAP Model 8 testing system** is not intended as a substitute for full polysomnography when additional parameters such as sleep stages or EEG activity are required. The target population consists of patients who are suspected of apnea and/or complain about snoring. The majority of the test procedures will take place at the patient's home, although some may take place in a sleep laboratory. Both pediatric and adult patients may be tested. CAUTION: US Federal law restricts this device to sale by or on the order of a physician. Use of this device must be under the direct supervision of a qualified adult (parent or	Minor differences: the Model 9 IFU clarifies the role of the device in providing data, and moves the Rx statement to be outside the Indications statement.

	Model 9-10000 device.	guardian) or health care practitioner trained in the use of the **SNAP Model 8** device.	
Intended population	Pediatric and adult.	Pediatric and adult.	None
Common or usual name	Sleep apnea home sleep test (HST)	Sleep apnea home sleep test (HST)	None
Regulatory Class	Class II	Class II	None
Classification name and product code	868.2375 Breathing frequency monitor MNR	868.2375 Breathing frequency monitor MNR	None

III. Technological Characteristics

Technological Characteristic	**Snap SAM Model 9-10000**	**Snap Model 8 (K110064)**	**Differences**
Respiratory Measurement	Effort, Flow (14Hz) Audio (2240Hz)	Effort, Flow (14Hz) Audio (2240Hz)	None
Oximeter Measurement	SpO2, Pulse Rate (14Hz)	SpO2, Pulse Rate (14Hz)	None
Body Position Channel	6 discrete positions: Upright, Inverted, Prone, Supine, Left, Right Sampling Rate: 14 Hz	5 discrete positions: Upright, Prone, Supine, Left, Right Sampling Rate: 14Hz	Additional position available in Model 9 -10000. Accelerometer is integral to the device in the Model 9-10000 and is an external accessory in the Model 8. Both are mounted on the strap in the center of the patient's chest.
Controls	On/Off button (After on button press, Record starts after fixed delay)	On/Off Record	Record button not needed in Model 9-10000 as recording automatically starts after a fixed delay.
Control type:	Pushbutton	Pushbutton	None
Indicators	LED	LED and LCD	Model 9-10000 uses LED indicators only.
Effort Sensor	Integral to device Sample Rate: 14 Hz Gain 0.3 +/- 0.1 at 1Hz Output Amplitude: 0-2.4V (1.2V +50mV/-30mV baseline) Frequency Response:	External accessory Sample Rate: 14 Hz Gain 0.3 +/- 0.1 at 1Hz Output Amplitude: 0-2.4V (1.2V +50mV/-30mV baseline) Frequency Response: DC	The Model 9-10000 electronics are in the same enclosure as the effort sensor. Both devices, use the same effort sensor

	DC to 7-16Hz (14Hz nominal)	to > 7 Hz (14Hz nominal)	components, are worn on the chest, and attach to the same strap
Oximeter	External wireless connection to wrist worn Nonin 3150 or Wellue Checkme O2 Max	Internal Nonin OEMIII module, wired connection to finger probe.	Predicate device used internal Nonin OEMIII module. Model 9-10000 connects via BLE to external wrist-worn Nonin 3150 (cleared under K102350) or Wellue Checkme O2 Max (cleared under K191088) oximeters.
Oximeter Specifications	Nonin 3150: SpO2: 0-100%, +/- 2 digits 70-100% PR: 18-321 BPM, +/- 3 digits (Meets 80601-2-61:2011) Wellue: SpO2: 0-100%, +-2 digits 80-100%, +/- 3 digits 70-80% PR: 30-250 BPM +/- 2% or 2 digits (whichever is greater) (Meets 80601-2-61:2011)	Nonin OEMIII: SpO2 0-100%, +/- 3 digits 70-100% PR: 18-300 BPM, +/- 3 digits (Meets 80601-2-61:2011)	SpO2 and Pulse rate accuracy of the oximeters used with the Model 9-10000 are the same or better than the oximeter used with the Model 8.
Microphone	External accessory	External Accessory	Microphones are identical except for the connector.
Audio Specifications	Bandwidth: 20Hz - 760Hz Sampling Rate: 2240Hz Bit Resolution: 12-bit Dynamic Range: 2V	Bandwidth: 20Hz - 760Hz Sampling Rate: 2240Hz Bit Resolution: 12-bit Dynamic Range: 2V	None
System Dimensions	0.57 inches (H) 2.17” (W) 1.65” (D)	1.375 inches (H) 5.5 inches (W) 4 inches (D)	Model 9-10000 is smaller.
Operating Ambient Temperature	5 to 40 deg C	5 to 32 deg C	Model 9-10000 has a wider tested temperature range per IEC 60601-1-11.
Operating Ambient Humidity	15 to 85% non-condensing	20 to 60% non-condensing	Model 9-10000 has a wider tested humidity range per IEC 60601-1-11.
Power	3.6V Rechargeable	AC 100-240V 50-60Hz	Model 9-10000

	Lithium Battery	3.6V Lithium backup	uses battery power only
Data Storage	Internal Flash Memory	Removable Flash Memory card	Data is stored on internal Flash memory on the Model 9-10000 and extracted through the USB port rather than through a removable Flash memory card.
File Format	Snap Diagnostics proprietary	Snap Diagnostics proprietary	None.
External Interfaces	USB - Charging and Factory interface BLE – SpO2 Connection and Factory Interface to authorized external device.	USB – Factory Interface	Model 9-10000 has an additional BLE interface for connecting to the Oximeters and to the authorized external device.

IV. Discussion of Similarities and Differences

The two systems are substantially equivalent in their regulatory parameters including indications for use, intended population, regulatory class, classification name and product code. The two systems are substantially equivalent with respect to the implementation of most features, including:

- Respiratory effort, flow, and audio measurement. Circuits, gain, frequency response, resolution, accuracy, and sampling rate are identical.
- SpO2 and pulse rate measurement using cleared third party oximeters.
- The presence of a body position channel.
- On/Off controls.
- Status indicators (LED or LCD).
- Storage of recordings to flash memory
- The presence of communication interfaces.

The two systems also utilize the same cannula, cannula strap, microphone, and belt. They produce identical recording file structures.

The two systems differ in the following respects:

- The Model 9-10000 oximeter source has changed from that of the predicate. Data resolution and sampling rate are the same.
- An additional discrete position is available in the Model 9-10000 compared to the predicate, and the accelerometer has been made integral to the device.
- The Record button is not needed in the Model 9-10000 as recording automatically starts after a fixed delay.
- The Model 9-10000 uses LED indicators only.
- The Model 9-10000 electronics are in the same enclosure as the effort sensor.

Both the Model 9-10000 and the predicate use the same effort sensor components, are worn on the chest, and attach to the same strap.
- While the predicate device used an internal Nonin OEM module, the Model 9-10000 connects via BLE to external wrist-worn Nonin 3150 (cleared under K102350) or Wellue Checkme O2 Max (cleared under K191088) oximeters.
- SpO2 and Pulse rate accuracy of the oximeters used with the Model 9-10000 are the same or better than the oximeter of the predicate.
- The Model 9-10000 is smaller than the predicate.
- The Model 9-10000 has a wider tested temperature range than the predicate per IEC 60601-1-11.
- The Model 9-10000 has a wider tested humidity range than the predicate per IEC 60601-1-11.
- The Model 9-10000 uses battery power only.
- Data is stored on internal Flash memory on the Model 9-10000 and extracted through the USB port rather than through the removable Flash memory card of the predicate.
- The Model 9-10000 has an additional BLE interface for connecting to the oximeters and to the authorized external device.
- These differences do not materially affect product safety, efficacy, technological basis, or use.

Non-Clinical and/or Clinical Tests Summary

Comparative performance evaluations between the Snap SAM Model 9-10000 and the predicate device, the Snap Model 8 (K110064), demonstrated that the two devices are substantially equivalent in performance.

In addition, comprehensive performance testing according to the following standards and guidelines were conducted:
- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems (Edition 3.2 2020-08 Consolidated Version)
- IEC 60601-1-11 Medical electrical equipment - Part 1-11: 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 (Edition 2.1 2020-07 Consolidated Version)
- IEC 60601-1-2 Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – requirements and tests (Edition 4.1 2020-09 Consolidated Version)
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (Fifth Edition 2018-08)
- IEC 62133-2 Secondary cells and batteries 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 (Edition 1.0 2017-02)

Bench testing confirmed that the device met design requirements and the requirements of applicable standards.

Conclusions

The two devices have substantially equivalent intended uses and the same main classification. They have many of the same features. They are used on the same populations. The two products are different in minor ways that do not materially affect their technological basis or use.

Based upon comparisons of regulatory parameters, software features, amplifier features, and comparative performance evaluations, the Snap SAM Model 9-10000 is substantially equivalent to the predicate device, the Snap Model 8 (K110064).