DE NOVO CLASSIFICATION REQUEST FOR OWLET DREAM SOCK

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Infant pulse rate and oxygen saturation monitor for over-the-counter use.** An infant pulse rate and oxygen saturation monitor for over-the-counter use is a device that uses photoplethysmography to measure pulse rate and oxygen saturation in infants. The device may contain alarms that alert the caregiver when vital sign(s) go outside preset threshold(s).

NEW REGULATION NUMBER: 21 CFR 870.2705

CLASSIFICATION: Class II

PRODUCT CODE: QYU

BACKGROUND

DEVICE NAME: Dream Sock

SUBMISSION NUMBER: DEN220091

DATE DE NOVO RECEIVED: December 14, 2022

SPONSOR INFORMATION:

Owlet
3300 N. Ashton Blvd
Suite 300
Lehi, UT 84043

INDICATIONS FOR USE

The Dream Sock is indicated as follows:

> The Dream Sock analyzes photoplethysmography data to identify instances when the infant's pulse rate (PR) and/or oxygen saturation (SpO2) moves outside a preset range, and provides a notification to the caregiver, prompting them to assess the infant. The Dream Sock also displays the infant's PR and SpO2 values to the caregiver and displays trends in these measured values, and their relationship to the preset ranges, over time. These PR and SpO2 notifications and displays on the Dream Sock are intended for use in infants who are 1 to 18 months of age and between 6 to 30 lbs.

The Dream Sock is intended for over-the-counter (OTC) use only in a home environment. It is not intended to provide notification for every episode of the unexpected occurrences of elevated or depressed PR or a low SpO2 level; rather, the feature is intended to provide a notification only when sufficient data are available for analysis. The notifications and associated data can be used to supplement the decision by caregivers to seek additional guidance for medical care of the infant. The feature is not intended to replace traditional methods of monitoring, diagnosis or treatment.

The Dream Sock is not intended for use with infants previously diagnosed with cardiovascular or respiratory disease or conditions.

LIMITATIONS

The Dream Sock does not detect, diagnose or reduce Sudden Infant Death Syndrome (SIDS) or Sudden Unexpected Infant Death (SUID).

The Owlet Dream Sock is not a substitute for adult supervision or safe sleep practices.

The Dream Sock is not intended to diagnose, cure, treat, alleviate, or prevent any disease or condition.

Alternate between feet every 8 hours and also after recharging the Sensor. Check the child's foot often for any signs of irritated skin.

The Dream Sock is not for babies and children with ongoing health conditions.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Dream Sock uses photoplethysmography (PPG) on the infant's foot to measure the continuous pulse rate (PR) and oxygen saturation (SpO2) in the home environment. The device is intended to monitor healthy infants 1 to 18 months of age and between 6 to 30 lbs. The device includes alarms to alert the caregiver that the pulse rate or SpO2 has gone outside a preset range. The alarm thresholds are pulse rate <50 or >220 bpm and the SpO2<80%. The device calculates the outputs during times of motion and non-motion. The device includes 3 components: the sock hardware, the base station and mobile application. The wearable connects to the base station via Bluetooth (BLE).

The Sock

The Sock is the skin-contacting component that contains the PPG sensor and accelerometer. The accelerometer is used in signal quality algorithm. If too much motion is detected, then no measurement will be output. The PR and SpO2 algorithms are housed on the Sock. The

algorithm uses a 10 second rolling window of the PPG data to calculate a measurement every second. The Sock communicates with the Base station using Bluetooth.

Base Station
The Base Station receives the readings and status from the sensor. When the PR and/or SpO2 measurement goes outside the preset threshold(s), a visual and auditory alarm will sound alerting the caregiver. When the caregiver acknowledges the alarm, the top of the base station is clicked to silence the alarm. The base station communicates with the Cloud which communicates with the phone application through WIFI. Additionally, this is used to charge the sensor.

Mobile Application
The mobile application displays the measurements and trend graphs of previous data. A new measurement is displayed every 5 seconds on the mobile application. If the base station alarms, the mobile application will display a notification.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

Biocompatibility testing was performed according to FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process." The sponsor tested cytotoxicity, skin sensitization and skin irritation of the sock. The sponsor tested according to the guidelines for long-term, intact skin contact. Due to the device failing cytotoxicity testing until 1:8 dilution, the sponsor provided acute systemic toxicity, and material mediated pyrogenicity testing to support safety of the device in the fragile population.

Test	Purpose	Method	Acceptance Criteria	Results
Cytotoxicity	To identify any cytotoxic effects to the patient	ISO 10993-1	Grade ≤2	PASS at 1:8 dilution
Sensitization	To identify tissue reactions from the patch	ISO 10993-1	No evidence of tissue reaction	PASS
Irritation	To identify tissue irritation	ISO 10993-1	No evidence of tissue irritation	PASS
Acute Systemic Toxicity	To identify health hazards likely to arise due to acute exposure	ISO 10993-11	No unscheduled deaths; no weight loss >10%	PASS
Material Mediated Pyrogenicity	Detection of material mediated pyrogenicity	ISO 10993-11	Animals survive and are healthy via temperature monitoring	PASS

See clinical section for skin observation study that was used to support the safe use of the device in the intended use population.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

The Dream Sock conforms to the FDA-recognized standards for basic safety and essential performance of Medical Electrical Equipment. These standards include:

- IEC 60601-1-2:2014- Medical Electrical Equipment, Part 1-2: General requirements for safety- Collateral Standard: Electromagnetic compatibility- Requirements and tests
- IEC 60601-1:2006 + A1:2013- Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
- ASNI C63.27:2017- American National Standard for Evaluation of Wireless Coexistence
- AAMI TIR69:2017- Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
- IEC 60601-1-11:2015/AMD1:2020- 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

SOFTWARE

The Dream Sock has a Major Level of Concern (LOC). Appropriate documentation was provided to support the validation of the software for Major LOC in accordance with the FDA Guidance Document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," (issued May 11, 2005).

PERFORMANCE TESTING – BENCH

Test	Purpose	Method	Acceptance Criteria	Results
Pulse Amplitude (PA)	Verify the accuracy of the PA compared against the simulator value & verify PR and SpO2 is accurate at different Pas	3 devices were tested with a simulator and the PR, SpO2, and PA were measured by the DUT	≤(b)(4)% A_{RMS} AND As the simulator PA rises from (b)(4)%, the ΔPR≤1bpm & Simulator PA: ΔSpO2 (b)(4)%≤PA: ≤(b)(4)% (b)(4)%≤PA<(b)(4)%: ≤(b)(4)% (b)(4)%≤PA<(b)(4)%: ≤(b)(4)%	PASS

Pulse Rate Accuracy Test	To evaluate the pulse rate performance for the full claimed range	ISO 80601-2-61 Clause 201.12.1.104	$A_{RMS} \leq$ [redacted] bpm	PASS
Alarm Testing	Ensure alarm functionality works as intended	Testing was performed according to 60601-1-8:2006+ AMD1:2012+AMD2:2020		PASS

SUMMARY OF CLINICAL INFORMATION

USABILITY TESTING

Usability Testing was provided in accordance with the FDA Guidance Document, "Applying Human Factors and Usability Engineering to Medical Devices- Guidance for Industry and Food and Drug Administration Staff" (issued February 02, 2016).

Twenty (20) participants belonging to a user group of lay caregivers participated in the human factors validation study. The testing was performed in a simulated- use environment using a sequence of tasks. All subjects responded to critical tasks by responding to the infant upon annunciation of notification events. Correct response included assessing the infant's condition and correcting the root cause of the notification.

Skin Observation Study

A prospective study was performed to support the safety of the Dream Sock hardware, the Sock. The study included 43 participants with an average age was 7.0±4.7 months. Thirty participants wore the device for at least 48 hours. The skin was checked every 4 hours for any skin irritation. The skin reactions were evaluated for severity. Three skin reactions occurred in 2 of the 43 participants leading to an estimated rate of reactions per person per week of 0.16 (95% CI 0.01, 0.40). All skin reactions were determined to be a severity of 1 (Slight indentation or mild color change (pink/slightly darker)).

Breathe Down Study

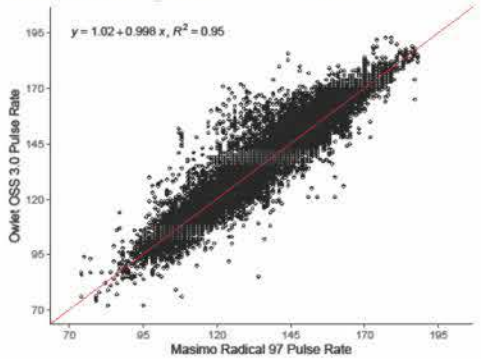
A Breathe-down study was performed in 18 healthy adults over the age of 18 years using an invasive pulse oximetry and the Masimo pulse oximeter. The performance of the device across the 70-100% SpO2 range was assessed in adults because it is unethical to induce lower SpO2 in infants. The device was placed on the subject's hand and simulated motion and non-motion imitations. The pulse rate and SpO2 were collected. The accuracy was provided for motion and non-motion simulations. The results are shown in the table below. The results for the SpO2 met the acceptance criteria of RMS<3% for the non-motion and motion simulations. The results for the PR met the acceptance criteria of the RMS<5bpm for the non-motion and motion simulations.

	Non-motion (RMS)	Motion (RMS)
SpO2	2.51	2.46
Pulse Rate	2.47	2.54

At-Home Study

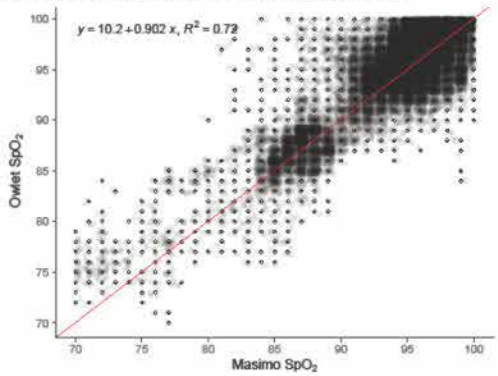
A clinical study was performed on subjects between post menstrual age>44 weeks and ≥18 months who weigh 6-30 lbs. The device was tested in 35 subjects who are independent from the algorithm training set. The results show that the SpO2 and pulse rate had an average root mean square (A_{rms}) of 2.16% and 3.53 bpm, respectively.

Figure 11.2 Masimo Radical 97 and Owlet OSS 3.0 PR Agreement



Note: regression model does not consider dependence of repeated measures.

Figure 11.3 Masimo Radical 97 and Owlet OSS 3.0 % Oxygen Agreement



Note: regression model does not consider dependence of repeated measures.

NICU Study

A prospective, single center, clinical study was conducted to support the alarm functionality. Subjects postmenstrual age<44 weeks in the NICU were monitored with the device for 48 hours. The skin under the Sock was inspected every 4 hours and the device is switched between feet every 8 hours. Sixty-six patients were continuously monitored with the Dream Sock, hospital grade pulse oximeters and electrocardiogram (ECG). In addition to the skin irritation observations, this testing was used to provide information about the alarm functionality at the preset thresholds. The specificity for the bradycardia and oxygen desaturation thresholds were 100% and 99.86%, respectively. This analysis indicates that the risk of false positive alarms is low.

Signal Quality Scoring in Pediatrics

Signal Quality was evaluated with patients in the Skin Observational Study and the At-Home study for a total of 70 patients. A full range of Fitzpatrick scale was included. Data were collected during various levels of activities with different intensities. The results showed evidence of no deterioration based on skin tone, or foot/ankle circumference within the intended use population. There was minimal deterioration based on movement.

LABELING

The labeling of the device satisfies the special controls listed below:

- A description of what the device measures and outputs to the user;
- Instructions for proper placement of the device;
- Instructions on care and cleaning of the device;
- Recommended actions based on device outputs to the user;

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the infant pulse rate and oxygen saturation monitor for over-the-counter use and the measures necessary to mitigate these risks.

Identified Risks to Health	Mitigation Measures
Poor quality incoming photoplethysmography signal resulting in failure to detect pulse rate (PR) and oxygen saturation (SpO2)	Clinical performance testing Human factors testing Electrical safety testing Electromagnetic compatibility testing Labeling
Misinterpretation and/or over-reliance on device output, leading to failure to seek treatment despite acute symptoms	Human factors testing Labeling
Adverse tissue reaction	Clinical performance testing Biocompatibility evaluation Human factors testing Labeling
False positive leading to unnecessary medical procedures	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Human factors testing Labeling
False negative resulting in failure to detect high or low pulse rate event and/or low SpO2 level event	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Human factors testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the infant pulse rate and oxygen saturation monitor for over-the-counter use is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include the following:
    (i) Evaluation of the effect of confounding variables, like skin pigmentation, on performance; and
    (ii) Demonstration of the consistency of the output and representativeness of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment; and
    (iii) Evaluation of all adverse events, including skin irritation.
(2) Software verification, validation, and hazard analysis must be performed. Documentation must include:
    (i) Technical specifications of the software, including software algorithm(s) and its inputs and outputs; and
    (ii) Specification of acceptable incoming sensor data quality control measures.
(3) Non-clinical performance testing must demonstrate the ability of the device to detect adequate photoplethysmography signal quality and validate any alarms.
(4) The skin-contacting components of the device must be demonstrated to be biocompatible.
(5) Performance testing must support the electrical safety and electromagnetic compatibility (EMC) of the electrical components of the device.
(6) Human factors and usability testing must demonstrate the following:
    (i) The caregiver can correctly use the device based solely on reading the device labeling; and
    (ii) The caregiver can correctly interpret the device outputs and understand next steps to take based on the outputs.
(7) Labeling must include:
    (i) Instructions for identifying the intended use population of the device, including populations where the device should not be used, and conditions of monitoring;
    (ii) A description of what the device measures and outputs to the caregiver, including instructions for the interpretation of results and appropriate actions;
    (iii) Situations in which the device may not operate at an expected performance level; and
    (iv) Instructions for cleaning the device and cleaning frequency.

BENEFIT-RISK DETERMINATION

The risks of the device include unnecessary medical attention, over-reliance on the device outputs, and misinterpretation of the device output. Unnecessary medical attention ("false positive") may result in caregiver's reaching out to medical professionals when treatment is not necessary, which uses unnecessary medical resources leading to the clinician's workload being disrupted. Over-reliance on the device outputs ("false negative") may result in delay of treatment, missed interventions. Additionally, due to the fragile skin of the intended population, skin irritation may occur if the device is worn incorrectly or not cleaned properly.

The device monitors the infant's pulse rate and SpO2, so it provides continuous vital sign monitoring of the healthy infant without clinician oversight. Also, the device provides additional information to the caregiver in addition to adult supervision.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> The Dream Sock analyzes photoplethysmography data to identify instances when the infant's pulse rate (PR) and/or oxygen saturation (SpO2) moves outside a preset range, and provides a notification to the caregiver, prompting them to assess the infant. The Dream Sock also displays the infant's PR and SpO2 values to the caregiver and displays trends in these measured values, and their relationship to the preset ranges, over time. These PR and SpO2 notifications and displays on the Dream Sock are intended for use in infants who are 1 to 18 months of age and between 6 to 30 lbs.
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> The Dream Sock is intended for over-the-counter (OTC) use only in a home environment. It is not intended to provide notification for every episode of the unexpected occurrences of elevated or depressed PR or a low SpO2 level; rather, the feature is intended to provide a notification only when sufficient data are available for analysis. The notifications and associated data can be used to supplement the decision by caregivers to seek additional guidance for medical care of the infant. The feature is not intended to replace traditional methods of monitoring, diagnosis or treatment.
>
> The Dream Sock is not intended for use with infants previously diagnosed with cardiovascular or respiratory disease or conditions.

The probable benefits outweigh the probable risks for the Dream Sock. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Dream Sock is granted and the device is classified as follows:

> Product Code: QYU
> Device Type: Infant pulse rate and oxygen saturation monitor for over-the counter use
> Regulation Number: 21 CFR 870.2705
> Class: II