November 8, 2023

Owlet Baby Care, Inc.
% Nada Hanafi
Senior Vice President
Veranex, Inc.
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: DEN220091
Trade/Device Name: Dream Sock
Regulation Number: 21 CFR 870.2705
Regulation Name: Infant pulse rate and oxygen saturation monitor for over-the-counter use
Regulatory Class: Class II
Product Code: QYU
Dated: December 14, 2022
Received: December 14, 2022

Dear Nada Hanafi:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Dream Sock, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> 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 Dream Sock 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 Dream Sock 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Dream Sock, and substantially equivalent devices of this generic type, into Class II under the generic name infant pulse rate and oxygen saturation monitor for over-the-counter use.

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).

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 14, 2022, FDA received your De Novo requesting classification of the Dream Sock. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Dream Sock into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Dream Sock can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Poor quality incoming photoplethysmography signal resulting in failure to detect pulse rate (PR) and oxygen saturation (SpO2) ok,	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

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.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the infant pulse rate and oxygen saturation monitor for over-the-counter use they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Kimberly Crowley at 301-796-6017.

Sincerely,

for Kenneth J. Cavanaugh -S

Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health