March 30, 2023

Happiest Baby, Inc.
℅ Allison Komiyama
Vice President
RQM+
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: DEN210039
Trade/Device Name: SNOO Smart Sleeper
Regulation Number: 21 CFR 880.5690
Regulation Name: Infant supine sleep system
Regulatory Class: Class II
Product Code: QTG
Dated: September 17, 2021
Received: September 20, 2021

Dear Allison Komiyama:

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 SNOO Smart Sleeper, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> The SNOO Smart Sleeper bassinet plus the SNOO Sleep Sack are jointly intended to facilitate a supine position during sleep. Infants who are placed in a supine sleep position are at lower risk of SIDS/SUID. The device is intended for home use by caregivers of infants from birth to 6 months of age, who are not yet able to roll over consistently.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the SNOO Smart Sleeper, and substantially equivalent devices of this generic type, into Class II under the generic name infant supine sleep system.

FDA identifies this generic type of device as:

> **Infant supine sleep system**. An infant supine sleep system is a device intended to facilitate a supine position during sleep for use in infants that are not yet able to roll over consistently. Infants placed in a supine sleep position are at lower risk of sudden infant death syndrome (SIDS) or sudden unexpected infant death (SUID).

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 September 20, 2021, FDA received your De Novo requesting classification of the SNOO Smart Sleeper. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SNOO Smart Sleeper 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 SNOO Smart Sleeper 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:

Risk to Health	**Mitigation Measures**
Increased risk of death, including from inadequate securement or inadequate positioning of the infant	Clinical data Postmarket surveillance Non-clinical performance testing Labeling
Inappropriate securement leading to • Injuries, contusions, or bruising • Entrapment • Respiratory compromise or suffocation • Gastroesophageal reflux • Plagiocephaly (“flat head syndrome”) • Death	Clinical data Postmarket surveillance Labeling
Inappropriate or inadequate securement due to device degradation over time (wear and tear, laundering)	Non-clinical performance testing Labeling
Inappropriate use or inadequate securement due to use error and/or improper fit	Clinical data Human factors assessment Labeling
Injury due to unstable device (tipping, rocking, improper placement)	Non-clinical performance testing Labeling
Infection	Labeling
Adverse tissue reaction (e.g., dermatitis)	Biocompatibility evaluation Labeling

In combination with the general controls of the FD&C Act, the infant supine sleep system is subject to the following special controls:

(1) Premarket clinical information and, as determined by FDA, postmarket surveillance data acquired under anticipated conditions of use must be collected to fulfill the following:
  (i) Demonstrate that the device holds the infant on the back;
  (ii) Provide data on adverse events (including deaths and injuries) and malfunctions to demonstrate the device can be safely used in the intended use population; and
  (iii) Provide data to demonstrate that use of the device does not increase the rate of SIDS/SUID in the intended use population.

(2) Human factors testing must demonstrate that the user can safely and correctly use the device.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be conducted:
  (i) Testing to ensure the mechanical and structural stability of the device and demonstrate that the device does not present a tipping hazard due to mechanical failures; and
  (ii) Material compatibility testing to demonstrate that the cleaning instructions provided by the manufacturer do not cause crazing, cracking, or deterioration of the device.

(5) Labeling must include:
  (i) Unless clinical performance data demonstrates that it can be removed or modified, a prominent warning that the device has not been demonstrated to reduce the risk of SIDS/SUID. Such warning must appear prominently on all labeling;
  (ii) A summary of available clinical information with the device, including a discussion of adverse events;
  (iii) A warning that the device is only indicated for use with infants who cannot consistently roll over;
  (iv) Instructions to ensure proper fit;
  (v) Instructions for cleaning the device; and
  (vi) Information regarding safe sleep practices to ensure the safe use of the device, including:
    (A) Recommendations for safe sleep environments; and
    (B) The level of supervision necessary to monitor a sleeping infant.

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 supine sleep system 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 Kathleen Fitzgerald at 301-796-6292.

Sincerely,

William H. Maisel -S

William H. Maisel, MD, MPH
Director, Office of Product Evaluation and Quality
CDRH Chief Medical Officer
Center for Devices and Radiological Health
Food and Drug Administration