DE NOVO CLASSIFICATION REQUEST FOR SNOO SMART SLEEPER

REGULATORY INFORMATION

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).

NEW REGULATION NUMBER: 21 CFR 880.5690

CLASSIFICATION: Class II

PRODUCT CODE: QTG

BACKGROUND

DEVICE NAME: SNOO Smart Sleeper

SUBMISSION NUMBER: DEN210039

DATE DE NOVO RECEIVED: September 20, 2021

SPONSOR INFORMATION:

Happiest Baby, Inc.
3115 S. La Cienega Blvd.
Los Angeles, California 90016

INDICATIONS FOR USE

The SNOO Smart Sleeper is indicated as follows:

> 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.

LIMITATIONS

The SNOO is demonstrated to facilitate a supine position during sleep; however, the SNOO has not directly demonstrated a reduction in the incidence of SIDS/SUID.

This device is only indicated for use with infants who cannot consistently roll over.

The device is not a substitute for adult supervision.

Do not use this product if the infant can push up on hands and knees, can roll over consistently, or has reached 6 months of age, whichever comes first.

DEVICE DESCRIPTION

The SNOO Smart Sleeper (SNOO) is comprised of the SNOO bassinet and the SNOO Sleep Sack that jointly constitute an infant securement device intended to facilitate a supine position during sleep. 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.

The SNOO Sleep Sack is a cotton swaddle with fixed wings made of woven cotton fabric that extend to the right and left of the infant's body. Three sizes of sleep sacks (small 5-12lbs, medium 12-18lbs, and large 18-25lbs) are provided with each bassinet to accommodate the growing baby. Small loops at the end of each SNOO Sleep Sack wing are slid over the safety clips of the SNOO bassinet to securely position the swaddled infant on the back. The SNOO Sleep Sack has corresponding wings that are designed to be physically attached to those clips - after the baby is wrapped in the sleep sack - thereby keeping the infant securely positioned on the back during sleep and to prevent rolling.

The SNOO bassinet also provides sound and motion. White noise and rocking can be automatically increased in response to a baby's cries. There is a SNOO App which can be used to adjust the levels of motion.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The patient-contacting components of the SNOO Smart Sleeper (SNOO) include the SNOO bassinet fitted sheet and the SNOO Sleep Sack. The SNOO bassinet fitted sheet is made of 100% cotton, and the SNOO Sleep Sack is made of 95% cotton and 5% elastane, and features mesh panels made of 100% polyester. Biocompatibility testing was performed on the patient contacting components of the SNOO. Testing included Cytotoxicity testing per ISO 10993-5:2009 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*, sensitization testing per ISO 10993-10:2010 *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*, and irritation testing per ISO 10993-23:2021 *Biological Evaluation of Medical Devices, Part 23: Tests for Irritation* on the final finished device.

SHELF LIFE

Durability of the SNOO Sleep Sack's zipper and safety loops were evaluated. The effect of washing over the expected lifecycle of the SNOO Sleep Sack and SNOO bassinet fitted sheet was assessed. Use life testing was completed to demonstrate a use life of 6 months.

ELECTROMAGNETIC CAPABILITY & ELECTRICAL SAFETY

Electrical safety testing was performed in accordance with the following standards:

- BS EN 61558-1 Safety of transformers, reactors, power supply units and combinations thereof - General requirements and tests
- BS EN 61558-2-16 Safety of transformers, reactors, power supply units and combinations thereof - Part 2-16: Particular requirements and tests for switch mode power supply units and transformers for switch mode power supply units for general applications.
- UL 1310 - Class 2 Power Units CAN/CSA C22.2 No. 223 - Power Supplies with Extra-low Voltage Class 2 Outputs.

Electromagnetic compatibility (EMC) testing was conducted per the FDA Recommended Standard IEC 60601-1-2. The SNOO Smart Sleeper demonstrated that it complies with the emission limits conducted for CISPR 11. Additionally, conducted and radiated emissions testing was performed per CFR 47 FCC Part 15, Subpart B, which included EMC testing to the same frequencies (0.15 MHz- 30MHz) and acceptance limits as IEC 60601-1-2.

PERFORMANCE TESTING – BENCH

The SNOO Smart Sleeper bassinet was tested in accordance with ASTM F2194-16e1 (Standard Consumer Safety Specification for Bassinets and Cradles) and 16 CFR 1218 (Requirements for bassinets and cradles).

The SNOO Sleep Sack was tested as described in the table below.

Test Performed	Device Description / Sample Size	Test Method	Acceptance Criteria	Results (PASS/ FAIL)
Zipper Durability Test	10 zippers / batch	Open and close the zipper 500 times at an approximate speed of 10cm/sec.	500 cycles without any jamming or breaking issues.	PASS
Loop Hook & Unhooking	3 SNOO Sacks (1 Small, 1 Medium, 1 Large)	Perform 500 hook and unhook cycles on SNOO Sleep Sack elastic loops to the safety clips, per the IFU instructions.	Visual Inspection for deterioration of components after 500 hook and unhook cycles.	PASS
Washing Durability Test	10 pieces / batch	Utilizing any commercial large washing machine and household clothes drying machine, wash and dry the Sleep Sack for 100 cycles. After every 10 cycles, measure the dimensions.	Dimension deviates less than 10%, except for safety clip width (<5%).	PASS
Velcro Durability Test	10 pieces / batch	After a wash and dry cycle, perform open and close cycles on the hook (male) and loop (female) Velcro strips.	Velcro adheres at 360 uses.	PASS

HUMAN FACTORS USABILITY TESTING

A Human Factors validation study was completed in accordance with the FDA 2016 guidance "Applying Human Factors and Usability Engineering to Medical Devices". The study encompassed a series of scenarios in a simulated use environment that contained tasks related to use of the system by its intended users. The scenarios were tied to the risk analysis process and included user tasks that are typically done when using the system. Fifteen test participants were evaluated on tasks that included unpacking the SNOO, setting up the system, swaddling a baby (doll) in the SNOO Sleep Sack, securing the baby (doll) in the SNOO bassinet, and properly removing the baby (doll) from the device. The validation study met the acceptance criteria and was deemed acceptable.

SUMMARY OF CLINICAL INFORMATION

Happiest Baby provided real world evidence (RWE) showing a rate of supine sleep position of approximately 98.7% in 1012 users (confidence interval [97.8%,99.2%]). In addition, over 93 hours of video recordings showed all observed infants remaining in a supine position during their time in the SNOO. In addition, Happiest Baby provided real-world evidence on 106,723 SNOO users and compared the incidence of reported SIDS/SUID in SNOO users to historical data from the CDC Wide-ranging Online Data for Epidemiological Research (WONDER) database. Although the data was not of sufficient quality to determine a precise SIDS/SUID rate, it did demonstrate that the device did not increase the risk of SIDS/SUID in the study population.

The following adverse events, including serious adverse events, have been reported at or below expected rates when using the SNOO Smart Sleeper: death, gastroesophageal reflux, plagiocephaly, aspiration, contusion, and dermatitis.

POSTMARKET SURVEILLANCE

The clinical data described above were collected in the United States but did not evaluate the device in a population that is reflective of the entire US population, including the US subpopulations at highest risk of SIDS/SUID. A section 522 postmarket surveillance study will therefore be required to obtain a more comprehensive safety profile of the device by collecting safety data associated with use of the device in US subpopulations at higher risk of SIDS/SUID to determine the rates of serious injury and death for high-risk infants when they use the SNOO Smart Sleeper. Safety data will be collected and provided in updated labeling.

LABELING

The device labeling includes the following:

a. On the packaging and in directions for use, a prominent warning that the device has not been demonstrated to reduce the risk of SIDS/SUID;
b. A summary of available clinical data with the device, including a discussion of adverse events;
c. A warning that the device is only indicated for use with infants who cannot consistently roll over;
d. The level of supervision necessary to monitor a sleeping infant in the intended use environment;
e. Recommendations for safe sleep environments;
f. Instructions and guidelines to ensure proper fit of the infant into the sleep system; and
g. Instructions for maintaining and reprocessing the device.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of an Infant Supine Sleep System.

Risk and Mitigation 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	Clinical data Postmarket surveillance Labeling

Risk to Health	Mitigation Measures
• Respiratory compromise or suffocation • Gastroesophageal reflux • Plagiocephaly ("flat head syndrome") • Death	
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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

The probable benefits of the device are based on clinical data, as described above. The data demonstrated that the SNOO Smart Sleeper secures the infant in a supine position during sleep. Infants who are placed in a supine sleep position are at lower risk of SIDS/SUID (Moon, R. Y., et al. (2022). "Sleep-Related Infant Deaths: Updated 2022 Recommendations for Reducing Infant Deaths in the Sleep Environment." Pediatrics 150(1).).

The probable risks of the device are also based on clinical data. A securement device that is misused or poorly fitted presents risks to the infant such as entrapment, suffocation, and SIDS/SUID. Plagiocephaly, also known as flat head syndrome, may occur as a result of placement in the supine position for an extended period of time. Gastroesophageal reflux was also observed. These two were the most common risks. Contusion, aspiration and dermatitis were also observed, but to a lesser extent.

The data collected for the SNOO Smart Sleeper did not demonstrate that use of the device decreased the risk of SIDS/SUID, and the device was not extensively studied in infants demographically at highest risk of SIDS/SUID. However, the data did demonstrate that the device could secure an infant on its back. Safe to Sleep guidelines state that placing infants on the back to sleep is associated with lower rates of SIDS/SUID (https://safetosleep.nichd.nih.gov/). The risks reported from the study were well understood and in line with historical data and clinical experience. Therefore, FDA has determined that while additional data are necessary to further assess the benefits and risks of the device in the most vulnerable infants, the benefits of the device outweigh its risks as studied.

In order to mitigate the risks of a securement device, caregivers should read the directions for use carefully and ensure that the device is used accordingly and with appropriate supervision. Safe to Sleep guidelines continue to recommend that an infant be placed on its back to sleep with no other objects in the crib.

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 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.

The probable benefits outweigh the probable risks for the SNOO Smart Sleeper. 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 SNOO Smart Sleeper is granted and the device is classified as follows:

Product Code: QTG
Device Type: Infant supine sleep system
Regulation Number: 21 CFR 880.5690
Class: II