DE NOVO CLASSIFICATION REQUEST FOR PRAPELA SVS HOSPITAL BASSINET PAD (MODEL P01)

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Therapeutic vibrational mattress pad. A therapeutic vibrational mattress pad is a reusable hospital mattress pad with integrated mechanical vibrations to be used as adjunctive therapy for neonates and infants.

NEW REGULATION NUMBER: 21 CFR 880.5151

CLASSIFICATION: Class II

PRODUCT CODE: QVY

BACKGROUND

DEVICE NAME: Prapela SVS hospital bassinet pad (model P01)

SUBMISSION NUMBER: DEN240031

DATE DE NOVO RECEIVED: June 17, 2024

SPONSOR INFORMATION:

Prapela, Inc.
2 Main ST.
STE 15-219
Biddeford, Maine 04005

INDICATIONS FOR USE

The Prapela SVS hospital bassinet pad is indicated as adjunctive non-pharmacological therapy in newborns ≥37 weeks gestational age exposed prenatally to opioids with neonatal opioid withdrawal syndrome (NOWS).

The Prapela SVS hospital bassinet pad is indicated for prescription use only.

LIMITATIONS

The sale, distribution, and use of the Prapela SVS hospital bassinet pad are restricted to prescription use in accordance with 21 CFR 801.109.

Newborns meeting the following criteria should not be treated:

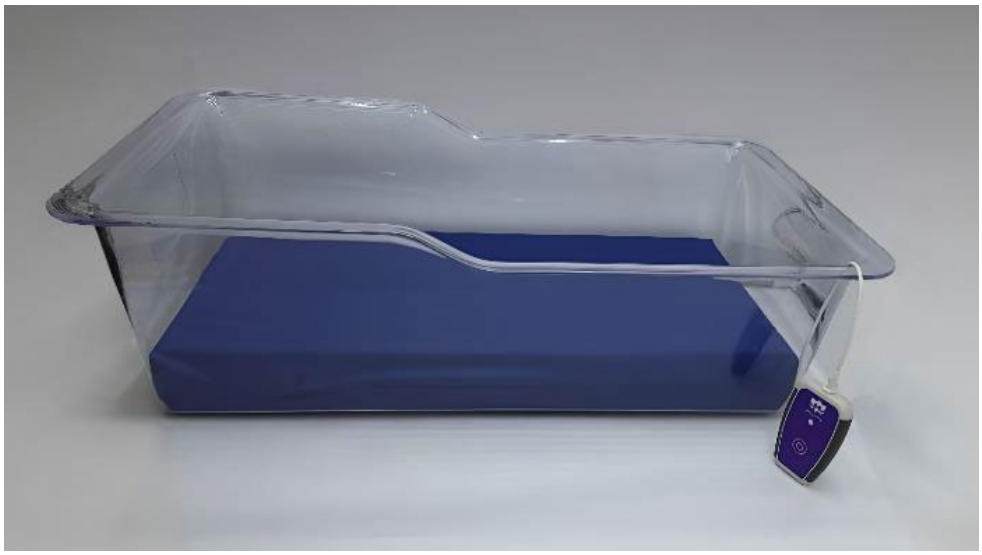
- Born less than 37 weeks
- Has a clinically significant congenital abnormality
- Has a clinically significant fetal anomaly
- Has hydrocephalus or intraventricular hemorrhage >grade 2
- Has a seizure disorder not related to drug withdrawal
- Has a clinically significant cardiac shunt
- Has anemia (hemoglobin<8g/dL)
- Has hypoxic ischemia encephalopathy
- Has respiratory failure that requires invasive ventilatory support
- Has methicillin-resistant Staphylococcus aureus (MRSA) or receiving treatment for bacterial or viral conditions

The device is intended to be used in a professional healthcare setting with temperature-controlled environments, including but not limited to neonatal care step-down units, hospital patient rooms (next to mother's bedside), and offsite specialty centers treatment centers with mother/child patient rooms that provide treatment for newborns diagnosed with Neonatal Opioid Withdrawal Syndrome (NOWS)/Neonatal Abstinence Syndrome (NAS). The device should not be used in isolated oxygen rich environments or in or near any radiological imaging device.

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

DEVICE DESCRIPTION

The Prapela Stochastic Vibrotactile Stimulation (SVS) hospital bassinet pad (model P01) is a non-sterile, reusable, mattress pad that has a transducer embedded in the foam of the mattress. The transducer is located in the center of the pad and produces small-input stochastic stimulations that resonate through the foam of the pad. The pad comes with a hand-held control unit that toggles the vibrations on and off. When the vibrations are turned on, the stimulation cycles in 3 hours ON/OFF cycle. The mattress pad is designed to fit most standard hospital grade bassinets.



SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The Prapela SVS hospital bassinet pad (model P01) is classified as intact skin-contacting with a prolonged contact duration. Biocompatibility was evaluated in accordance with ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and FDA Guidance *Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* Biocompatibility testing was conducted per the following standards to support the biological safety of the device:

- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin Sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation

The results of these evaluations support that the biological risks of the device have been adequately mitigated.

REPROCESSING, STERILITY & SHELF LIFE

The Prapela SVS hospital bassinet pad (model P01) is not provided sterile. Performance testing after accelerated aging confirmed the Prapela SVS hospital bassinet pad (model P01) maintained device performance over the 6-month labeled shelf life. Reprocessing and disinfection instructions for the end user were provided and were evaluated per the 2015 FDA guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* under clinical worst-case conditions. Cleaning and disinfection validation studies were provided and met the recommendations of the guidance.

ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

The Prapela SVS hospital bassinet pad (model P01) conforms to the requirements for electrical safety and electromagnetic compatibility (EMC) of the following standards:

- IEC 60601-1-1:2005 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests.

HUMAN FACTORS

Prapela conducted human factors testing by recruiting 18 clinicians located in neonatal care step-down units for NOWS diagnosed newborns to assess their ability to set up, utilize, and clean-up & reprocess the mattress pad. The testing was conducted based on FDA 2016 guidance *Applying Human Factors and Usability Engineering to Medical Devices*. The participants were successful in setting up and using the Prapela SVS hospital bassinet pad (model P01) with neonates. Major tasks included assembling the device in the bassinet basket, turning on the device, cleaning the pad, and disassembling and storing the device. The human factors testing report supports the participants were able use the device for the intended use within the expected use environments.

SOFTWARE

The Prapela SVS hospital bassinet pad (model P01) contains software to control the feedback loop for vibration delivery. The firmware is responsible for device startup/initialization, control of ON/OFF function, and generation of a signal that is passed to device hardware for vibration delivery. The firmware generates a random signal in the specified frequency range that is passed to a potentiometer on the device circuit board. The overall amplitude of the pad surface vibration, referred to as Displacement Root Mean Square (DRMS), is set by the potentiometer. There are no other user interactions with the firmware. Software verification, validation, and analysis was performed, and the results demonstrate that the software functions as intended, and the required specifications are met. The device's software has a Basic Documentation Level.

A cybersecurity evaluation was not needed as the device does not connect to external networks or devices.

PERFORMANCE TESTING – BENCH

The functionality of the Prapela SVS hospital bassinet pad (model P01) was evaluated using multiple performance tests. The following table is a summary of the functional tests that were performed:

Test Name	Purpose	Method	Acceptance Criteria	Results
Vibration Displacement and Frequency	Evaluate the vibrational	(b) (4)	(b) (4)	All results were passing.

Test Name	Purpose	Method	Acceptance Criteria	Results
	functionality of the device	(b) (4)	(b) (4)	
Effect of patient weight on stimulation	Ensure that the shaking from the vibrations is not excessive for the infant or subdued by the weight of the infant			All results were passing.

Test Name	Purpose	Method	Acceptance Criteria	Results
Dimensional Testing	Evaluate the dimensions of the pad and ensure gaps are not formed on the edges of the compatible bassinets.	(b) (4)	(b) (4)	All results were passing.
Stimulation Uniformity Test	Evaluate the uniformity of the stimulation across the mattress			All results were passing.
Auditory Sound Level	To evaluate the sound pressure levels produced by the device and ensure that they are within acceptable limits.			All results were passing.

SUMMARY OF CLINICAL INFORMATION

Data from two clinical studies conducted with the Prapela SVS hospital bassinet pad were submitted to provide reasonable assurance of the safety and effectiveness of the device:

Study 1:

Bloch-Salisbury E, Wilson JD, Rodriguez N, et al. Efficacy of a Vibrating Crib Mattress to Reduce Pharmacologic Treatment in Opioid-Exposed Newborns: A Randomized Clinical Trial. JAMA Pediatr. Jul 1 2023;177(7):665-674. doi:10.1001/jamapediatrics.2023.1077

This study was a prospective, randomized controlled trial assessing the following primary endpoints: administration of morphine treatment, cumulative morphine dose, and hospital length of stay. A total of 181 opioid-exposed newborns completed the study of which 94 infants were treated with SVS, and 87 infants received standard of care treatment. Of the 181 infants, 60 infants received morphine treatment. The authors carried out a post-hoc analysis on 32 infants receiving and responding to morphine treatment, comparing SVS treatment (n = 17) and standard of care treatment (n = 15). Results of the post-hoc analysis showed improvement in length of treatment and cumulative morphine dose administered in patients that were found to be responsive to morphine treatment and received SVS treatment.

Study 2:

Zuzarte I, Indic P, Barton B, Paydarfar D, Bednarek F, Bloch-Salisbury E. Vibrotactile stimulation: A non-pharmacological intervention for opioid-exposed newborns. PLoS One. 2017;12(4):e0175981. Doi:10.1371/journal.pone.0175981

This study enrolled 26 opioid-exposed newborns and evaluated the movement activity, heart rate, respiratory rate, axillary temperature, and the blood oxygen saturation levels. While these clinical endpoints were not appropriate to provide a reasonable assurance of effectiveness for the indications for use of this device, information on adverse events, such as those related to thermoregulation and blood-oxygen desaturation levels, were also collected as an endpoint of the study. No adverse events were reported in the study and the infants were reported to be able to maintain their body temperatures and oxygen levels throughout the study. Therefore, these results provided additional support for the safety of the device.

Both studies were conducted in a hospital environment on newborns with prenatal opioid exposure at a gestational age of greater than or equal to 37 weeks and receiving morphine treatment. Baseline characteristics such as sex, race, ethnicity, gestational age, or birth weight were not evaluated by the sponsor for potential association with safety and effectiveness outcomes. The studies were not specifically powered for any relevant subgroups, and no additional subgroup analyses were performed.

Pediatric Extrapolation

Pediatric extrapolation was not needed to support the intended use population because the pediatric age ranges in the clinical study are the same as the pediatric age range in the intended use population.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with the use of a therapeutic vibrational mattress pad.

Risks to Health	**Mitigation Measures**
Sleep disruption or hearing loss due to inappropriate vibrations or high auditory sound levels	Clinical performance data Software verification, validation, and hazard analysis Non-clinical performance testing
Ineffective treatment from worsening of signs and symptoms during use of the device or return of symptoms after discontinuation of the device, and inappropriate placement of infant on pad	Clinical performance data Software verification, validation, and hazard analysis Labeling
Inappropriate use or inadequate securement of pad in bassinet leading to injury by: • strangulation by cords or straps • entrapment in gaps around pad/against the bassinet	Non-clinical performance testing Labeling
Electrical shock or burns	Electrical safety testing
Interference with other medical devices	Electromagnetic compatibility (EMC) testing
Adverse tissue reaction	Biocompatibility evaluation
Infection	Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the therapeutic vibrational mattress pad is subject to the following special controls:

(1) Clinical performance data must include information from adverse events and performance endpoints in support of the indications for use in the intended patient population under clinically relevant use scenarios.
(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and environment(s) of use. Testing must include:
    (i) Verification and validation of the vibration mechanism output of the device;
    (ii) Verification and validation of auditory sound levels of the device; and
    (iii) Dimensional testing to demonstrate compatibility with compatible neonatal hospital beds/bassinets.
(3) Performance testing must demonstrate electrical safety and electromagnetic compatibility (EMC) of the device in the intended use environment.
(4) Software verification, validation, and hazard analysis must be performed for any software components of the device.
(5) The patient-contacting components of the device must be biocompatible.

(6) Labeling must include:
   (i) Instructions to ensure proper fit and infant placement;
   (ii) A list of compatible neonatal hospital beds/bassinets;
   (iii) Instructions for cleaning and disinfection; and
   (iv) Warnings related to suffocation and strangulation risks related to straps and cords.

BENEFIT-RISK DETERMINATION

Summary of Benefits
Based on the clinical evidence provided, the Prapela SVS hospital bassinet pad (model P01) demonstrated probable benefit as a non-pharmacological adjunctive treatment option to decrease the length of treatment and cumulative doses of morphine in NOWS patients that are found to be responsive to morphine treatment. This population presents a challenge to treat given NAS/NOWS symptomology. In addition, the sponsor provided qualitative data to support a probable benefit that the device can reduce the burden on health care providers providing supportive care for opioid exposed neonates and infants by reducing the time spent holding and rocking the baby.

Summary of Risks
While no adverse events were observed in the clinical performance data, risks associated with the device include sleep disruption and hearing loss due to inappropriate vibrations or high auditory sound levels, ineffective treatment, inappropriate use or inadequate securement of the pad in the bassinet, strangulation due to the length of the electrical cord or entrapment (i.e., patient may roll over and get stuck in corners of the pad), electrical shock or burns, adverse tissue reaction, and infection due to the reusable nature of the device. These risks have been adequately mitigated through clinical performance data, non-clinical performance testing, EMC and electrical safety testing, biocompatibility evaluation, and labeling.

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, the data support that, for the indications for use stated above, the probable benefits outweigh the probable risks for the Prapela SVS hospital bassinet pad (model P01). The device provides benefits and the risks can be mitigated by the use of general and special controls.

CONCLUSION
The De Novo request for the Prapela SVS hospital bassinet pad (model P01) is granted and the device is classified as follows:

Product Code: QVY
Device Type: Therapeutic vibrational mattress pad
Regulation Number: 21 CFR 880.5151
Class: II