

April 4, 2025

Prapela, Inc.  
John Konsin  
Chief Executive Officer  
2 Main ST STE 15-219  
Biddeford, Maine 04005

Re: DEN240031

Trade/Device Name: Prapela SVS hospital bassinet pad (model P01)

Regulation Number: 21 CFR 880.5151

Regulation Name: Therapeutic vibrational mattress pad

Regulatory Class: Class II

Product Code: QVY

Dated: January 15, 2025

Received: January 15, 2025

Dear John Konsin:

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 Prapela SVS hospital bassinet pad (model P01), a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Prapela SVS hospital bassinet pad is indicated as adjunctive non-pharmacological therapy in newborns  $\geq 37$  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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Prapela SVS hospital bassinet pad (model P01), and substantially equivalent devices of this generic type, into Class II under the generic name Therapeutic Vibrational Mattress Pad.

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.

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 June 17, 2024, FDA received your De Novo requesting classification of the Prapela SVS hospital bassinet pad (model P01). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Prapela SVS hospital bassinet pad (model P01) 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 Prapela SVS hospital bassinet pad (model P01) 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:

<b>Risks to Health</b>	<b>Mitigation Measures</b>
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: <ul style="list-style-type: none"> <li>• strangulation by cords or straps</li> <li>• entrapment in gaps around pad/against the bassinet</li> </ul>	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

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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](mailto: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 Therapeutic Vibrational Mattress Pad 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto: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 Sarah Hanif at 240-402-2275.

Sincerely,

Michael Hoffmann  
Director  
OHT3: Office of Gastrorenal, ObGyn,  
General Hospital, and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health