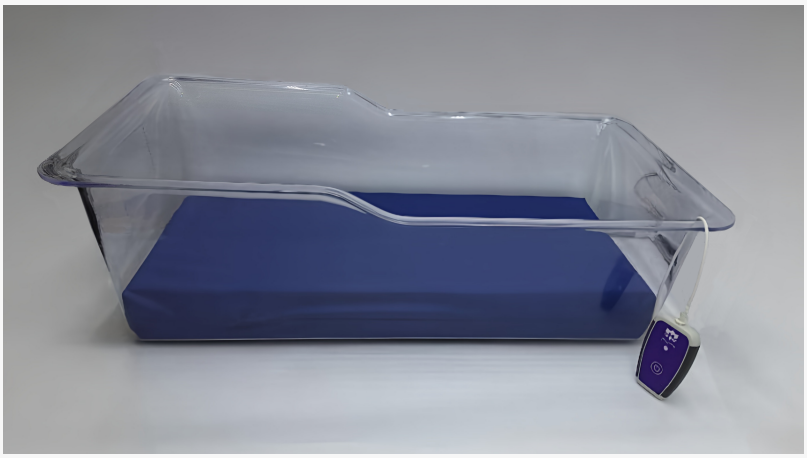
Prapela, Inc. Granted FDA De Novo for Breakthrough Therapy Helping the Most Vulnerable Victims of our Opioid Epidemic

Prapela's SVS hospital bassinet pad is the first and only therapeutic medical device to treat opioid exposed newborns with neonatal opioid withdrawal syndrome.



Prapela SVS hospital bassinet basked inside a standard-size bassinet basket

PORTLAND, ME, UNITED STATES, April 17, 2025 /EINPresswire.com/ -- One of the more sorrowful consequences of our opioid crisis is the use of opioids among pregnant women and their impact on newborns. Prenatal opioid exposure (POE) can result in a postnatal withdrawal condition in newborns called neonatal opioid withdrawal syndrome (NOWS). Babies with NOWS experience hyperirritability, sweating, irregular heart and breathing rates, fever, vomiting, and diarrhea.

On April 4, 2025, the FDA granted De Novo classification to the Prapela SVS hospital bassinet pad, making it the first and only medical device with FDA marketing authorization to treat NOWS. The device has the following indication 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.

The Prapela SVS hospital bassinet pad is a reusable, easy-to-use, vibrating pad designed to fit snugly in standard-sized medical bassinets used in hospitals worldwide.

"Having family and friends impacted by the opioid epidemic, it is a great honor to introduce this

breakthrough," said John Konsin, Prapela Co-founder and CEO. "This landmark achievement was made possible through the support of dedicated professionals and grants from the National Institute on Drug Abuse (NIDA) at the National Institutes of Health and the Wyss Institute at Harvard University."

Dr. David Paydarfar, Prapela Co-founder and currently Chair of the Department of Neurology at Dell Medical School, UT Austin, began developing the therapy in 1995. He added, "Stochastic vibration's ability to stabilize newborns is well documented. Now, with FDA authorization, its benefits can reach caregivers and infants who need it."

Elisabeth Bloch-Salisbury, Ph.D., Adjunct Associate Professor in the Department of Psychiatry at the University of Pittsburgh School of Medicine, pioneered the use of stochastic vibrotactile stimulation (SVS) technology as a therapeutic intervention for newborns with POE and was the lead researcher on a pivotal clinical trial published in JAMA Pediatrics. (1) She indicated, "Our findings validate the effectiveness of SVS as a complementary nonpharmacological treatment for newborns with NOWS. We are thankful to the nurses and families in the infant units at UMass Memorial Health Care and UPMC Magee-Women's Hospital who supported the study, and we are happy to hear that Prapela's device is authorized by the FDA to treat newborns with NOWS."

Dr. Rachana Singh, MD, MS, Interim Chief of Newborn Medicine at Tufts Medical Center, noted, "It is exciting to have another option for newborns that can deliver consistent care and complement skin-to-skin and other soothing interventions."

Don Ingber, MD, PhD, Founding Director of the Wyss Institute for Biologically Inspired Engineering at Harvard University, added "We are delighted with Prapela's recent milestone bringing an innovative bioinspired technology initially invented at the Wyss Institute in collaboration with UMass Chan Medical School and Massachusetts General Hospital all the way from the lab bench to the bedside where it can positively impact the lives of infants who desperately need more effective therapies."

The American Academy of Pediatrics (AAP) indicates non-pharmacological interventions as the first-line treatment for NOWS. (2) These treatments, such as swaddling, rooming-in, and skin-to-skin care, require intensive caregiver interaction, which is often not sustainable. As a result, practitioners often resort to using products not designed or evaluated by the FDA to treat newborns with NOWS. With the introduction of the Prapela SVS hospital bassinet pad, health care professionals can eliminate the risk of using unproven consumer products with NOWS babies.

About Prapela

Prapela, Inc. is a pediatric medical device company focused on improving infant health with proprietary stimulation therapy. Since 2018, the company has been awarded two FDA Breakthrough Device Designations, a Challenge Award, and two Small Business Innovation Research (SBIR) grants (R43DA049300 & R44DA049300) from the National Institute on Drug

Abuse of the National Institutes of Health for NOWS. The company is currently conducting a major pivotal study to reduce apnea and hypoxic events in preterm newborns. Health care professionals interested in more information on the Prapela SVS hospital bassinet are encouraged to visit the company's website, www.prapela.com.

Research reported in this announcement was supported by the National Institute on Drug Abuse, part of the National Institutes of Health, through the NIH Small Business Innovation Research Grant Awards. The content is solely the authors' responsibility and does not represent the official views of the National Institutes of Health.

References:

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