January 18, 2018

Neonatal Loving Kare, Inc.
% Nicole Spaniel
Principal Specialist
Regulatory and Quality Solutions, Inc.
2790 Mosside Blvd #800
Monroeville, Pennsylvania 15146

Re: K172962
Trade/Device Name: Nurture Rest
Regulation Number: 21 CFR 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: Class I
Product Code: OUW
Dated: December 20, 2017
Received: December 22, 2017

Dear Nicole Spaniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172962

Device Name

Nurture Rest

Indications for Use *(Describe)*

The Nurture Rest (including models 100-1-O and 100-1-C) is indicated for premature infants undergoing oxygen therapy to maintain an airway and for whom treatment may be facilitated by this repositioning and stabilization device. The premature infants are being continuously monitored for oxygen saturation levels and heart rate in the Neonatal Intensive Care Unit (NICU) by medical professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY K172962

Neonatal Loving Kare's Nurture Rest

Sponsor: Neonatal Loving Kare, Inc.
1702 Treasure Lake
DuBois, PA 15801

Applicant: Nicole Sawyers, President
Neonatal Loving Kare, Inc.
1702 Treasure Lake
DuBois, PA 15801
Phone: 814-590-4519

Contact Person: Niki Spaniel, RAC, Regulatory Correspondent
R&Q Solutions, Inc.
Phone: 724-681-6050

Date Prepared: January 4, 2018

Regulation and Classification Information:

	Subject Device	**Predicate Device**
Proprietary Name:	Nurture Rest	RES-Q Infant Wedge & Sling
Manufacturer	Neonatal Loving Kare, Inc.	CR Enterprises, LLC
Common Name:	Pediatric Position Holder	Pediatric Position Holder
Classification Name:	Infant Positioner, Rx, Use In Highly Monitored Setting	
Classification:	Class 1	Class 1
Classification Panel:	General Hospital**:**	General Hospital**:**
Regulation Number:	21 CFR §880.5680	21 CFR §880.5680
Product Code:	OUW	FRP
510(k) Number:	K161983	K090284

Device Description

Nurture Rest is an infant sleep positioning device used by medical staff to position and secure premature infants in a prone, supine, or side position to limit mobility within an incubator in the neonatal intensive care unit (NICU). The Nurture Rest is shaped like the female anatomy in order to encourage a "Kangaroo Care" style positioning technique that mimics being held against a female body/chest while also keeping the infant's head, neck, and spine aligned. This device gives nurses a useful tool in their daily role of repositioning and caring for these special premature infants. The infants for whom the device is used are undergoing oxygen therapy to maintain an airway (intubation, nasal CPAP, bubble CPAP, high flow nasal cannula, or nasal cannula) and are continuously monitored for oxygen saturation levels and heart rate. The Nurture Rest consists of a washable, flame-retardant cloth material.

There are two models of the device (Models 100-1-O and 100-2-C). Both devices are appropriate for prone, supine and side positioning of premature infants. One model of the device (Model 100-1-O) has customizable opening at the head to allow for prone face-down positioning of micro-preemies for whom positioning with the head turned to the side would increase the chance of hemorrhaging due to increased intracranial pressure. The other model (Model 100-2-C) does not have an opening and is for prone with head turned positioning. The device comes with pillows to help stabilize the infant and swaddling straps to minimize motion of the arms and body of the infant. As with standard NICU practices, the Nurture Rest enables the infant to be re-positioned and treated as needed (typically every 4 to 6 hours), which allows NICU staff to cluster care in order to let the infants rest and grow in between physical and emotional stimulation.

Intended Use

The Nurture Rest is intended for the positioning of premature infants who are in the Neonatal Intensive Care Unit (NICU).

Indications for Use

The Nurture Rest (including models 100-1-O and 100-1-C) is indicated for premature infants undergoing oxygen therapy to maintain an airway and for whom treatment may be facilitated by this repositioning and stabilization device. The premature infants are being continuously monitored for oxygen saturation levels and heart rate in the Neonatal Intensive Care Unit (NICU) by medical professionals.

Contraindications: The Nurture Rest is contraindicated for the following:

- Healthy, stable neonate
- Home use;
- Use in the prone position for any patient having an umbilical or venous line;
- Use on infants who are not on oxygen therapy to maintain an airway;
- Use on an infant who is not being continuously monitored for oxygen saturation levels and heart rate;
- Use under radiant warmer systems may present overheating issues
- Do not use with phototherapy systems

Technological Characteristics of the Nurture Rest

The Nurture Rest allows professional caregivers to place and hold infants in the prone, side and supine positions (developmental care) to provide comfort to premature infants in the NICU. It contains bindings and enclosures to safely hold the infant in position. See Table 1 for a comparison between the predicate and subject device.

The Nurture Rest consists of

- One Nurture Rest Positioning aid (open/face-down version or closed version)
- Two small pillows for assisting in positioning infant
- Swaddling straps (two in the closed model, three straps for the face-down version
- Bendy bar for face down version
- Boundary pocket at bottom of Nurture Rest for infant's feet and legs

Table 1: Predicate and Subject Device Comparison Table

	PREDICATE DEVICE	**SUBJECT DEVICE:**
	RES-Q Infant Wedge & Sling	**Nurture Rest**
DEVICE IMAGE		 Model 100-1-O  Model 100-1-C ©Neonatal Loving Kare 2016
MANUFACTURER	CR Enterprises, LLC	Neonatal Loving Kare, Inc
REGULATION NUMBER	880.5680	880.5680
REGULATION MEDICAL SPECIALTY	General Hospital	General Hospital
REVIEW PANEL	General Hospital	General Hospital
FDA PRODUCT CODE	FRP	OUW
CLASSIFICATION	1	1
GMP Exempt	Yes	No
REGULATION DESCRIPTION	Pediatric Position Holder	Pediatric Position Holder

	PREDICATE DEVICE RES-Q Infant Wedge & Sling	SUBJECT DEVICE: Nurture Rest
INTENDED USE	The RES-Q Infant Wedge & Sling is designed to allow babies 0-12 months with gastro-esophageal reflux to rest comfortably in a semi-upright position; it is used for sleeping and playtime in supine, prone, and side-lying positions.	The Nurture Rest is intended for the positioning of premature infants who are in the Neonatal Intensive Care Unit (NICU).
INDICATIONS FOR USE	The RES-Q Infant Wedge & Sling is designed to allow babies 0-12 months with gastroesophageal reflux to rest comfortably in a semi-upright position; it is used for sleeping and playtime in supine, prone, and side-lying positions.	The Nurture Rest, Models (including models 100-1-O and 100-21-C,) is indicated for premature infants undergoing oxygen therapy to maintain an airway and for whom treatment may be facilitated by this repositioning and stabilization device. The premature infants are being continuously monitored for oxygen saturation levels and heart rate in the Neonatal Intensive Care Unit (NICU) by medical professionals.
CONTRA-INDICATIONS FOR USE	Unknown	Contraindications: The Nurture Rest is contraindicated for the following: • Healthy, stable neonate • Home use; • Use in the prone position for any patient having an umbilical or venous line; • Use on infants who are not on oxygen therapy to maintain an airway; • Use on an infant who is not being continuously monitored for oxygen saturation levels and heart rate; • Use under radiant warmer systems may present overheating issues; Do not use with phototherapy systems..

	PREDICATE DEVICE	SUBJECT DEVICE:
	RES-Q Infant Wedge & Sling	**Nurture Rest**
PHYSICAL DESCRIPTION	Washable and reusable vinyl-covered foam wedge that has a bibbed cotton sling that is attached with Velcro and holds the infant.	Nurture Rest consists of a washable, flame-retardant cotton flannel cloth material that is filled with a polyester batting. It provides cushioned support. It contains swaddling straps and a pocket to hold the infant.
INTENDED ENVIRONMENT FOR USE	Hospital and Home Use, In crib	Prescription Use in a Neonatal Intensive Care Unit (NICU) environment, in crib or isolette.
PATIENT POPULATION	Infants (premature and term) 0-12 with gastro-esophageal reflux	Premature infants in NICU who are on oxygen therapy to maintain an airway, and are continuously monitored for oxygen saturation levels and heart rate
TECHNOLOGY	Prone and Supine positioning to benefit conditions associated with premature and full term infants in the NICU, hospital or home.	Prone, Side and Supine positioning (developmental care) to provide comfort to premature infants in the NICU.
BIOCOMPATIBILITY	Unknown	ISO 10993-1 surface contact testing
STERILITY	Non-sterile	Non-sterile
SINGLE USE	No	No
SINGLE PATIENT USE	Unknown	Yes

Comparison Discussion of Predicate and Subject Devices

Technological Characteristics

Both the Nurture Rest and the RES-Q-Wedge use an orthopedic positioning pillow/mattress technology. The device technology consists of a soft interior housed by an exterior fabric which supports the weight of an infant during rest. Both devices use a “nesting” technology to provide boundaries and containment in order to facilitate good musculoskeletal alignment during rest and during developmental care positioning. The fabric of the Nurture Rest and the fabric that is used in the RES-Q-Wedge sling are both cotton fabrics.

The Nurture Rest technological characteristics differ from those of the RES-Q-Wedge in the shape of the device, the absence of the sling, as well as the exterior fabric as detailed below:

The RES-Q-Wedge technology is based on a firm wedge-shaped design that contains a sling into which the infant is secured. Due to the angle and density of the wedge, a sling is required to hold or "nest" the infant in place and maintain the angle of elevation. The RES-Q-Wedge is also intended to be reversible with the backside used during "tummy time," whereby an infant is placed in the prone position in order to build neck and arm muscles.

The Nurture Rest is indicated only for use on premature infants who are being cared for in the NICU environment and who are being monitored for heart rate and oxygen saturation 24/7. The Nurture Rest does not have an indication for "tummy time" or any home use, in fact home use is contraindicated for the Nurture Rest. Summative Usability Testing was performed via simulated use. This study demonstrated that the device was successfully able to be used to position, align and retain a doll which was representative of actual premature patients, and therefore, meet the intended use. Despite the differences in the indications for use, the subject device has demonstrated to be substantially equivalent to the predicate device.

Performance Data

Bench top testing was performed to confirm that the device is able to position an infant within the NICU. In all instances, the Nurture Rest functioned as intended and all test results observed were as expected.

Usability Testing was conducted to demonstrate that the intended user group could successfully use the device after watching the training DVD and reading the instructions for use. The summative usability study was completed to evaluate the usability of the Nurture Rest. The goal of the study was to ensure that NICU nurses can safely and effectively use the Nurture Rest as intended. The simulated use study focused on all anticipated interactions of the intended users with the device including positioning of infant patients (micro-preemie and preemie) using the Nurture Rest as well as care and maintenance of the device. This study demonstrated that the device was successfully able to be used to position, align and retain a doll which was representative of actual premature patients, and therefore, meet the intended use.

Biocompatibility testing was performed on the Nurture Rest to demonstrate that the materials are considered non-cytotoxic, non-irritating, and non-sensitizing. For characterization only, microbial testing was performed on the Nurture Rest to determine the bioburden of the device. The Nurture Rest was found to be non-cytotoxic, a non-irritant and did not elicit a sensitization response.

Durability Testing was performed to demonstrate that the product's shape shall still enable a user to position a Preemie doll per the instructions for use after 4 weeks of use.

Coefficient Friction Testing was performed to demonstrate that the Nurture Rest is comparable to other products that come into contact with patient skin in the NICU.

Bioburden Testing was performed to ensure that the Nurture Rest is comparable to other items that come into contact with patient skin in the NICU.

Storage testing was performed to ensure that the packaged device could withstand worst case storage scenarios.

Packaging and ship testing was performed to ensure that the packaged device could withstand worst case shipping scenarios.

Conclusion

Based on the intended use, technological characteristics and performance testing, the subject device has demonstrated to be substantially equivalent to the predicate device.