DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 24, 2017

Rapid Aid Corp.
% Diane Horwitz, Ph.D., RAC
Regulatory Consultant
Mandell Horwitz Consultants
2995 Steven Martin Dr.
Fairfax, Virginia 22031

Re: K163295
Trade/Device Name: Infant Transport Mattress Warmer with Disc
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or Cold Disposable Pack
Regulatory Class: Class I
Product Code: IMD
Dated: July 3, 2017
Received: July 3, 2017

Dear Dr. Horwitz:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K163295

Device Name
Rapid Aid Infant Transport Mattress Warmer with Disc

Indications for Use *(Describe)*
The Rapid Aid Infant Transport Mattress Warmer with Disc provides warmth during transport of an infant within the hospital or between hospitals. It is recommended for full-term infants.

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.

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510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Jeff Whitely, CEO
Rapid Aid Corp.
4120A Sladeview Crescent
Mississauga ON L5L 5Z3
CANADA

1.2 Official Correspondent

Diane Horwitz, Ph.D., RAC, Regulatory Consultant
2995 Steven Martin Dr.
Fairfax, VA 22031

Telephone: 703.307.2921
Fax: 703.242.1117
Email: dmh@mandellhorwitzconsulting.com

1.3 Date of Preparation

June 30, 2017

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

Rapid Aid Infant Transport Mattress Warmer with Disc

2.1.2 Common/Usual Name

Hot or cold disposable pack

2.1.3 Classification Information

Classification Name:	Hot or cold disposable pack
Classification Regulation:	21 CFR 890.5710
Class:	1
Product Code:	IMD
Panel:	Physical Medicine

3. PREDICATE DEVICE

The predicate device is Neo Nest Gel Infant Transport Mattress (DeNovo Products, K112547).

4. DESCRIPTION OF THE DEVICE

The Rapid Aid Infant Transport Mattress Warmer with Disc (Infant Transport Mattress) is a rectangular pad that is intended to provide warmth during transport of an infant within a hospital or between hospitals. The single-use disposable device consists of an outer pouch with a liquid solution activated by bending an activator disc; an exothermic reaction warms the Infant Transport Mattress to no higher than 104°F (range 101°F to 104°F) for a dwell time of ≥10 minutes.

5. INTENDED USE

The Intended Use / Indications for Use for the Rapid Aid Infant Transport Mattress Warmer with Disc (Infant Transport Mattress):

"The Rapid Aid Infant Transport Mattress Warmer with Disc provides warmth during transport of an infant within the hospital or between hospitals. It is recommended for full-term infants."

6. SUBSTANTIAL EQUIVALENCE OF THE RAPID AID INFANT TRANSPORT MATTRESS COMPARED TO THE PREDICATE

The Rapid Aid Infant Transport Mattress device and the predicate device have almost identical intended use statements and are planned for identical uses in the clinic. The technological characteristics of the Rapid Aid device and the predicate are also similar.

Table 1. SUBSTANTIAL EQUIVALENCE OF THE RAPID AID INFANT TRANSPORT MATTRESS DEVICE AND THE PREDICATE DEVICE

Characteristic	Predicate (K112547)	Subject Device Rapid Aid Corp. Infant Transport Mattress Warmer with Disc
Intended Use / Indications for Use Statement	"Provision of warmth during transport of infant within the hospital or between hospitals. Recommended for full term infants."	"The Rapid Aid Infant Transport Mattress Warmer with Disc provides warmth during transport of an infant within the hospital or between hospitals. It is recommended for full-term infants."
Single Use or Multiple Use	Single Use	Single Use
Sterile or Nonsterile	Nonsterile	Nonsterile
Bag Size	16 × 10 in. (160 sq. in.)	15.7 × 9.6 in. (151 sq. in.)
Bag Material	Unknown material with woven cloth material on bag	Polyethylene/60 g polyamide (PE/PA) with woven cloth material on bottom outside of bag
Contents of bag	Sodium acetate, water, thickener, activation disc; supersaturated solution	Sodium acetate, water, thickener, activation disc; supersaturated solution
Patient facing material	Non-woven cloth adhered to the	Non-woven cloth adhered to the

Characteristic	Predicate (K112547)	Subject Device Rapid Aid Corp. Infant Transport Mattress Warmer with Disc
	pouch	pouch
Disc Material	Stainless Steel	Stainless Steel
Activation	Activating Disc triggers the exothermic reaction	Activating Disc triggers the exothermic reaction
Performance Testing – Temperature	Temperature performance testing	Temperature performance testing to achieve temperature range of 101°F to 104°F and dwell time is ≥10 minutes
Performance testing for proper seal strength	Unknown	Device shall remain intact when subjected to 500 PSI for 30 sec.
Shipping testing	Passed	Passed
Biocompatibility testing	Not performed because not different from predicate	Performed Cytotoxicity, Irritation and Sensitization; passed

7. PERFORMANCE TESTING

The 510(k) submission provided performance data to establish the substantial equivalence of the Rapid Aid Infant Transport Mattress with Disc to the predicate device. A summary of these performance tests is provided below.

Performance Testing: The Infant Transport Mattress with Disc was tested for seal width, seal integrity (visual), weight, temperature after activation, dwell time, seal integrity and strength (pressure test), outer packaging thickness were all measured; all tests were a pass.

Biocompatibility Testing: The Infant Transport Mattress with Disc was tested for biocompatibility per ISO 10993-1 and was found to meet all applicable requirements.

Temperature Testing*:* Infant Transport Mattress with Disc has passed the pressure test and the temperature test after storage for 30 weeks in 40°C accelerated temperature conditions, which corresponds to 24 months of real time shelf life.

8. CONCLUSIONS

This 510(k) submission demonstrates that the Rapid Aid Infant Transport Mattress Warmer with Disc is substantially equivalent to the predicate device.