DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 27, 2015

Rapid Aid Corporation
c/o Mandell Horwitz Consultants, LLC
Diane Horwitz, Ph.D., RAC
2995 Steven Martin Drive
Fairfax, VA 22031

Re: K150627
Trade Name: Rapid Aid Instant Disposable Infant Heel Warmer
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: Class I
Product Code: MPO
Dated: April 27, 2015
Received: April 27, 2015

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 27f 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Felipe Aguel -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)*
K150627

Device Name
Rapid Aid Instant Disposable Infant Heel Warmer

Indications for Use *(Describe)*
Rapid Aid Infant Heel Warmer is primarily used in hospitals, doctor's offices, and other healthcare facilities. It is an instant warm pack intended to be used on an infant's heel to increase blood circulation to the area to aid in the drawing of blood for analysis. It is a single use, non-toxic, non-sterile, disposable warmer.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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"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 of Safety and Effectiveness

Manufacturer and Submitter

Company Name:	Rapid Aid Corp.
Company Address:	4120A Sladeview Crescent MISSISSAUGA ON L5L 5Z3 CANADA Telephone: (905) 820-4788 Fax: (905) 820-1649
Contact Person:	Rose Ren, QA/Regulatory Affairs Manager
Date Summary Prepared:	March 1, 2015

Device

Trade/Device Name:	Rapid Aid Instant Disposable Infant Heel Warmer - Disc
Common/Usual Name:	Infant Heel Warmer
Classification Name:	Infant Heel Warmer (Chemical Heat Pack)
Regulation Number:	21 CFR 890.5710
Product Code:	MPO
Classification Panel:	Physical Medicine
Classification:	Class I

Substantial Equivalence

The Rapid Aid Instant Disposable Infant Heel Warmer with Disc is substantially equivalent to the Rapid Aid Instant Disposable Infant Heel Warmer (K040856).

Device Description

The Rapid Aid Infant Heel Warmer is a self contained unit comprised of a flexible, poly/nylon outer pouch containing:

a) A metal disc that can be flexed during activation,
b) Liquid solution of food grade sodium acetate and water,
c) Minute crystals of sodium acetate.

An adhesive tape is attached to the top of the unit. The unit is activated by squeezing firmly on the inner fluid pouch, this will cause the inner perforated pouch to activate. Rapid crystallization occurs when the liquid contents are exposed to the minute crystals of sodium acetate contained within the poly/nylon outer pouch. This exothermnic reaction causes the unit to heat up to 104ºF. The adhesive tape strip is used to hold the warmer in place if desired.

Intended Use/Indications for Use

Rapid Aid Infant Heel Warmer is primarily used in hospitals, doctor's offices, and other healthcare facilities. It is an instant warm pack intended to be used on an infant's heel to increase blood circulation to the area to aid in the drawing of blood for analysis. It is a single use, non-toxic, non-sterile, disposable warmer.

Substantial Equivalence Analysis

The Infant Heel Warmer with Disc has the identical Intended Use and Indications for use as the predicate device. The basic technological characteristics remain the same, with the exception of the replacing an inner pouch for activation with a metal disc, to start the exothermic reaction.

Several other currently marketed Infant Heel Warmer products cleared by FDA use this method of activation. The modified device has been tested and it has been verified that product specifications are met. It is therefore concluded that the Infant Heel Warmer with Disc is substantially equivalent to the predicate device.

Performance - Bench Testing

The Infant Heel Warmer with Disc was tested against the predicate device to ensure conformance with temperature characteristics (maximum temperature and dwell time requirements). The average maximum temperature achieved was 102.6 ± 0.2 ºF (new device) and 102.2 ± 0.4 ºF (predicate) and the average dwell time that the unit was between 101 ºF and 104 ºF was 8.5 ± 1.0 min (new device) and 8.5 ± 0.8 min (predicate). The predicate and the new devices were both within the specified range for this device.

The materials that contact the skin have not changed:

- The outer poly/nylon pouch material has been tested following ASTM standards and is latex free and non-sensitizing.
- The finished packing material is tested for: thickness following ASTM D1203, tensile strength following ASTM D-882 and seal width. Pouch packaging material is subject to incoming inspection for width/length, seal integrity and burst strength.
- The chemical mixture claims are based on the results of testing the sodium acetate, which is a nontoxic, food grade chemical and has been found to be toxicologically acceptable for it's intended use.
- Finished product is subject to testing for peak temperature, seal integrity and pressure testing.

Date Summary Prepared: March 1, 2015