K040856

MAY - 3 2004

RAPID AID LTD.
4120 A Sladeview Crescent
Mississauga, ON L5L 5Z3
Canada

Phone: (905) 820-4788
Fax: (905) 820-1649

510(k) Summary
[As required by 807.92(c)]

Submitter of 510(k)	Rapid Aid Ltd. 4120 A Sladeview Crescent Mississauga, Ontario L5L 5Z3
Telephone	(905) 820-4788
Fax	(905) 820-1649
Regulatory Contact	Anna Olasz Q.A. & Regulatory Manager
Date Summary Prepared	March 2004
Product Trade Name	Rapid Aid Instant Disposable Infant Heel Warmer
Common or Usual Name	Infant Heel Warmer
Classification Name	Pack, Hot or Cold Disposable Class I, 21 CFR 890-5710 Panel: Physical Medicine Product Code: MPO
Predicate Devices	[870.92(a)(3)]

Device Name	510(k) Number
Medi-Heat Infant Heel Warmer	K032989
Baxter Sodium Acetate Infant Heel Warmer	K936084
Warm Gel Infant Heel Warmer by Prism	K912715

Description of the device

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

a) A flexible, perforated, polyethylene/polyester inner pouch that holds the liquid solution.
b) Liquid solution of food grade sodium acetate and water contained in a).
c) Minute crystals of sodium acetate.

510 (k)
Rapid Aid Infant Heel Warmer

Description Cont'd	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 exothermic reaction causes the unit to heat up to 105 degrees F. The adhesive tape strip is used to hold the warmer in place on the infant's heel.
Intended Use	The Rapid Aid Infant Heel Warmer is a single use, non-toxic, non-sterile, disposable device. It is an instant warm pack intended to be used on an infant's heel to aid in the drawing of blood for analysis.
Substantial Equivalence	The Rapid Aid Infant Heel Warmer is substantially equivalent to the Medi-Heat Infant Heel Warmer, Baxter Sodium Acetate Infant Heel Warmer, and the Warm Gel Infant Heel Warmer by Prism in that: - intended use is the same - performance attributes are the same - temperature output of the Rapid Aid Infant Heel warmer is within the range of the predicate devices - chemical composition is primarily the same in the predicate devices and the Rapid Aid Infant Heel Warmer; food grade sodium acetate and water - The Rapid Aid Infant Heel Warmer differentiates from the predicate devices in that it does not require a disc for activation, rather the exposure of the saturated sodium acetate solution to the sodium acetate crystals located in the outer pouch are the catalyst for the chemical reaction.
Summary of Testing	All materials used in the composition of the formulation are subject to testing at the supplier site and are accepted based on results from a Certificate of Analysis.

Summary of Testing Cont'd	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 non-toxic, 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. Summary of peak temperature from batch production results is attached.
Performance Data	The Rapid Aid Infant Heel Warmer was tested against predicate devices for temperature characteristics. They performed very similarly with temperatures within the same ranges, reaching a maximum temperature around 105 F within the first minutes and then steadily decreasing in temperature.

Conclusions drawn from testing:

The data from testing demonstrates that the performance of the Rapid Aid Infant Heel Warmer is very similar to and substantially equivalent to that of other commercially available Infant Heel Warmers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2004

Ms. Anna Olasz
Quality Assurance and Regulatory Affairs Manger
Rapid Aid Ltd.
4120 A Sladeview Crescent
Mississauga, Ontario
Canada L5L 5Z3

Re: K040856
Trade/Device Name: Rapid Aid Infant Heel Warmer
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: I
Product Code: MPO
Dated: March 26, 2004
Received: April 5, 2004

Dear Ms. Olasz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

RAPID AID INFANT HEEL WARMER
510(k) Notification

Indications for Use

510(k) Number (if known): 040856

Device Name: Rapid Aid Infant Heel Warmer

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.

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040856

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