K032989

OCT 2 2 2003

MediHEAT, Inc.

505 Hill Road
Dalton, GA 30722-2527

Phone: (706) 226-1800
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510(k) Summary
(As required by 807.92(c))

Submitter of 510(k)	**MediHeat, Inc 505 Hill Road Dalton GA 30722**
Telephone	**(706) 226-1800**
Fax	**(706) 226-2195**
Regulatory Affairs Contact	**Uma Ramachandran Director of Regulatory Affairs & QA**
Date Summary prepared	**September 2003**
Product Trade Name	**MediHEAT Infant Heel Warmer**
Common or Usual Name	**Infant Heel warmer**
Classification Name	**Pack, Hot or Cold Disposable 21 CFR 890-5710**
Predicate Devices	**[807.92(a)(3)]**

Device Name	510(k) Number
Instant Warm Gel Pack by Prism	K912715
Omni Warm Gel Pack	K936084
Baxter Sodium Acetate Infant Heel Warmer	K961154
DeRoyal Infant Heel Warmer	K954716
Tempra Heat Pack	K951383

510(k)
MediHEAT Infant Heel Warmer

Description of the device [807.92(a)(4)]	**The MediHeat Infant Heel Warmer is a self-contained unit comprised of a flexible Nylon/Polyethylene bag containing the ingredients:** **a) Food grade sodium acetate,** **b) Water and** **c) Activator disk.** **When the disk is clicked, it activates the sodium acetate solution causing it to pass from the liquid phase to a solid phase (crystallization), making it exothermic.** **d) An adhesive tape to hold the warmer in place.** **It heats up to a maximum temperature of up to 105°F and gradually diminishes.**
Intended Use [807.92(a)(5)]	**The MediHEAT Infant Heel Warmer is a single-use, non-toxic, non-sterile device. The MediHEAT Infant Heel Warmer is intended to be used on an Infant's heel to facilitate drawing blood for analyses.**
Substantial Equivalence:	**The chemical reaction involved in releasing the heat in MediHEAT Infant Heel warmer is substantially equivalent to PRISM Infant Heel warmer, Omni warm gel pack, Baxter sodium acetate infant heel warmer, DeRoyal infant heel warmer and Tempra heat pack in their intended use and performance characteristics.** **The temperature output of MediHEAT Infant Heel Warmer is well within the range of the predicate devices.**

Summary of studies and Technological Characteristics

Performance Characteristics:	**MediHEAT Infant Heel Warmer is tested against Predicate devices, bought in open market, in our lab for their temperature characteristics.**

Performance Characteristics (cont'd):

They all performed very similarly, i.e. the maximum temperature is up to 105°F. They lasted about 30 minutes and the temperature diminished gradually. The comparison graphs are given in Attachment F.

Conclusions drawn from studies:

The data from the studies conducted demonstrate that the performance of MediHEAT Infant Heel warmer is similar 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

OCT 2 2 2003

Ms. Uma Ramachandran
Director of Regulatory Affairs and Quality Assurance
MediHeat Inc.
505 Hill Road
Dalton, Georgia 30722

Re: K032989
Trade/Device Name: MediHEAT Infant Heel Warmer
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: I
Product Code: MPO
Dated: September 22, 2003
Received: September 24, 2003

Dear Ms. Ramachandran:

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) 594-1308. 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, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K032989

Device Name **MediHEAT Infant Heel Warmer**

Indications For Use:

1. MediHEAT Infant Heel Warmer is primarily used in hospitals, Doctor's offices, and other healthcare facilities.

2. Normally, Medical Practitioners squeeze the heels of Infants to increase blood circulation in the area before drawing blood for analyses.

3. The Infant Heel Warmer is used to warm the heel of an Infant to increase blood circulation to the area to facilitate blood sampling.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Milhous

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

510(k) Number K032984