HOMECARE DIVISION
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8560
Phone: 724-733-0200
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JAN 27 2004

K040044
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SECTION 9

510(K) SUMMARY

Date of Submission	December 15, 2003
Official Contact / Address of Manufacturing facility	Zita A. Yurko Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Phone: 724-387-4120 Fax: 724-387-4216
Proprietary Name	Heel Snuggler
Common/Usual Name	Infant Heel Warmer (Chemical Heat Pack)
Classification Reference	21 CFR 890.5710
Classification	Class I
Appropriate Classification Panel	Physical Medicine
Product Code	MPO
Predicate Device	DeRoyal Industries Infant Heel Warmer (K954716)
Reason for submission	Acquisition of Children's Medical Ventures resulted in 510(k) filing

Intended Use/Indications for Use

The Respironics Heel Snuggler infant heel warmer is intended for use whenever circulation needs to be stimulated in the infant heel in order for blood sampling to occur.

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Patient Population/Environment of Use

The Heel Snuggler is disposable and for single patient use only.

Substantial Equivalence

This traditional 510(k) submittal demonstrates that the Heel Snuggler is substantially equivalent to the DeRoyal Industries, Inc. Infant Heel Warmer (K954716).

Design verification tests were performed on the Heel Snuggler as a result of the risk analysis and the product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the differences between the Heel Snuggler infant heel warmer and the predicate infant heel warmer have no impact on the safety and effectiveness of the Heel Snuggler and that all hazards were successfully mitigated.

Device Description

The Heel Snuggler is a butterfly shaped packet that is filled with a non-toxic solution and a catalyst disk. Two straps with adhesive ends are attached to one side of the packet for securing the heel warmer to the infant's foot. Immediately following activation of the packet, the user rests the bottom of the infant's foot on the larger portion of the packet and holds the smaller portion of the packet to the ankle. The straps with adhesive tape on the end are then fitted across the infant's foot and ankle and secured to the opposite side of the packet. The adhesive portion of the strap is affixed to the packet only, not the infant's skin. This forms a boot shape around the infant's foot. The straps on the heel warmer are perforated, which enables the user to easily tear the straps and remove the heel warmer from the infant's foot after use.

When the catalyst disk inside the packet is flexed by the user, the catalyst reacts with the solution and initiates a chemical exothermic reaction, which produces warmth.

End of Section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2004

Respironics, Inc.
C/o Mr. Ned Devine
Entela, Inc
3033 Madison Avenue SE
Grand Rapids, Michigan 49548

Re: K040044
Trade/Device Name: Heel Snuggler Infant Heel Warmer
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: I
Product Code: MPO
Dated: January 12, 2004
Received: January 12, 2004

Dear Mr. Devine:

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

Indications for Use

510(k) Number (if known): K040044

Device Name: Heel Snuggler Infant Heel Warmer

Indications for Use:

Intended Use/Indications for Use

The Respironics Heel Snuggler infant heel warmer is intended for use whenever circulation needs to be stimulated in the infant heel in order for blood sampling to occur.

Patient Population/Environment of Use

The Heel Snuggler is disposable and for single patient use only.

for Mark N Milkerson

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...gical Devices

K040044

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)