SEP 19 2006

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K053254

1. Submitter's Identification:
Mr. Fangyi Liu
Shanghai Intco Medical Supply Co., Ltd.
1299 Hubin Road
Fengxian, Shanghai, 201417 P.R. China
Date Summary Prepared: Nov. 18, 2005

2. Name of the Device:
Shanghai Intco Medical Supply Co., Ltd.

Infant Heel Warmer by Intco

3. Predicate Device Information and Substantial Equivalence:
The Infant Heel Warmer by Intco is substantially equivalent in safety and effectiveness to the Rapid Aid Ltd., the Rapid Aid Infant Heel Warmer.

4. Intended Use:
The Infant Heel Warmer by Intco 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. The device is to be limited to use in hospitals, doctors' offices, and other healthcare facilities that administer health care services to newborns and infants. Prescription Use Only. The Indication for use of the Infant Heel Warmer by Intco is the same to the Rapid Aid Infant Heel Warmer, a legally marketed predicate device.

5. Device Description:

a. Classified by FDA's Physical Medicine Device Panel as Class I, 21 CFR 890.5710, Pack, Hot or Cold disposable, MPO, and meets all requirements of ISO 7176 and EN 1021.

b. The Infant Heel Warmer by Intco is a self contained unit comprised of a flexible, poly/nylon outer pouch containing:
I) A flexible, perforated, polyethylene/polyester inner pouch that holds the liquid solution.

II) Liquid solution of food grade sodium acetate and water contained in I).
III) 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 exothermic reaction causes the unit to heat up to 102 degree F. The adhesive tape strip is used to hold the warmer in place on the infant's heel.

6. Testing Report:
   a. 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.
      - The outer poly/nylon pouch material has been tested following ASTM standard 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 packing 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 testing for peak temperature, seal integrity and pressure testing. Summary of peak temperature from batch production results is attached.

   b. Performance Data:
      The Infant Heel Warmer by Intco was tested against predicate devices for temperature characteristics. They performed very similarly with temperature within the same range, reaching a maximum temperature around 105 F within the first minutes and then steadily decreasing in temperature.

   c. Conclusions drawn from testing:
      The data from testing demonstrates that the performance of the Infant Heel Warmer by Intco 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

Shanghai Intco Medical Supply Co., Ltd.
% Mr. John Zhao
Basic Medical Industries, Inc.
12390 East End Avenue
Chino, California 91710

SEP 19 2006

Re: K053254
Trade/Device Name: Infant Heel Warmer by Intco
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: Class I
Product Code: MPO
Dated: September 12, 2006
Received: September 13, 2006

Dear Mr. Zhao:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A

510(k) NUMBER (IF KNOWN) : K053254
DEVICE NAME: Shanghai Intco Medical Supply Co., Ltd.
INDICATIONS FOR USE: Infant Heel Warmer by Intco

The Infant Heel Warmer by Intco 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.

Prescription Use Only ✓
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____
(21 CFR 807 Subpart C)

Note: The device is to be limited to use in hospitals, doctor's offices, and other healthcare facilities that administer health care services to newborns and infants.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053254