October 6, 2022

International Biomedical
Amy Pieper
Director of Regulatory Affairs
8206 Cross Park Drive
Austin, Texas 78754

Re: K221653
Trade/Device Name: InfaTherm™ Disposable Infant Warming Mattress
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot Or Cold Disposable Pack
Regulatory Class: Class I, reserved
Product Code: IMD
Dated: June 7, 2022
Received: June 7, 2022

Dear Amy Pieper:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 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 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K221653

Device Name

InfaTherm™ Disposable Infant Warming Mattress

Indications for Use *(Describe)*

The InfaTherm™ Disposable Infant Warming Mattress is an instant warm pack intended to provide warmth during transport of an infant within the hospital or between hospitals. It is recommended for full-term infants. It is a single use, nontoxic, non-sterile, disposable device.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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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# 510(k) SUMMARY

Submitter Information:

International Biomedical
8206 Cross Park Drive
Austin, TX 78754
U.S.A.

Regulatory Affairs Contact:

Amy Pieper
Director of Regulatory Affairs
(512) 873-0033 - phone
(512) 873-9090 - fax

Date Summary Prepared: October 6, 2022

Device Identification:

Trade Names: InfaTherm™ Disposable Infant Warming Mattress
Common Name: Infant Warming Mattress
Regulatory Class: I
Regulatory Name: Hot or cold disposable pack
Regulatory Number: (21 CFR 890.5710)
Product Code: IMD
510(k) number: K221653

Predicate Device:

Rapid Aid Corp. – Infant Transport Mattress Warmer with Disc – K163295

Reference Device:

Omni Therm Inc.– Omni Warm Gel Packs – K936084

Device Description:

The InfaTherm™ Disposable Infant Warming Mattress is a single use, disposable pouch that is filled with a super saturated solution of food grade sodium acetate and water and a catalyst disk. When the catalyst disk inside the packet is flexed by the user, the catalyst disk reacts with the non-toxic solution and initiates a chemical exothermic crystallization of the sodium acetate, generating heat. When activated at 75°F, the Infant warming mattress will reach between 100-102°F and then gradually decrease in temperature over time.

The InfaTherm™ Disposable Infant Warming Mattress is rectangular in shape. Immediately following activation of the mattress, the user places the infant on the mattress.

Indications for Use:

The InfaTherm™ Disposable Infant Warming Mattress is an instant warm pack intended to provide warmth during transport of an infant within the hospital or between hospitals. It is recommended for full-term infants. It is a single use, nontoxic, non-sterile, disposable device.

Substantial Equivalence:

The substantial equivalence of the International Biomedical InfaTherm™ Disposable Infant Warming Mattress to the predicate is shown by similarity in intended use, indications for use, materials and performance. The table below provides a comparison of the technological characteristics of the subject device to the predicate.

| **System Specification** | **International Biomedical InfaTherm™ Disposable Infant Warming Mattress Subject Device** | **Rapid Aid Corp Infant Transport Mattress Warmer with Disc k163295 Predicate Device** | **Comparison** |
|---|---|---|---|
| Indications for Use | The InfaTherm™ Disposable Infant Warming Mattress is an instant warm pack intended to provide warmth during transport of an infant within the hospital or between hospitals. It is recommended for full-term infants. It is a single use, nontoxic, non-sterile, disposable device. | The Rapid Aid Infant Transport Mattress Warmer with Disc provides warmth during transport of an infant within the hospital or between hospitals. It is recommended for full-term infants. | Same |
| Environment of Use | Hospitals or between hospitals | Hospitals or between hospitals | Same |
| Prescriptive | Yes | Yes | Same |
| Pouch Material | Polyethylene LLDPE with white Polyester extrusion (PET) material on bottom of bag | Polyethylene/60g polyamide (PE/PA) with woven cloth material on bottom outside of bag | Similar – both devices utilize polyethylene pouches with a cloth material on the bottom. The predicate device does not provide enough detail on the cloth material to claim a complete match. Comparison between two devices does not indicate a material difference that would introduce any new issues of safety and effectiveness. |
| Solution Material | Sodium acetate (food grade), water, activation disc; supersaturated solution | Sodium acetate and water, thickener, activation disc; supersaturated solution | Similar – the subject device omitted the thickening agent that is used in the predicate. The thickening agent only serves to |

| System Specification | International Biomedical InfaTherm™ Disposable Infant Warming Mattress Subject Device | Rapid Aid Corp Infant Transport Mattress Warmer with Disc k163295 Predicate Device | Comparison |
|---|---|---|---|
| | | | make the gel more viscous when activated. Upon activation, the liquid becomes viscous by nature of the chemical reaction, a thickening agent is redundant. Omitting the thickening agent doesn't introduce any new issues of safety and effectiveness. |
| Activation Method | Activating Disc triggers the exothermic reaction | Activating Disc triggers the exothermic reaction | Same |
| Average Device Maximum Surface Temperature | 100-102°F | 101-104°F | Similar – Subject Device average temperature has a slightly lower peak temperature. Lower peak temperature doesn't introduce any new issues of safety and effectiveness. |
| Average Skin Surface Temperature | 101°F | Not Publicly Available | Similar – The predicate device does not publish the skin surface temperature, but the subject device temperature is in line with or slightly lower than the predicate for device surface temperature and there is a strong correlation in this type of product between the device surface temperature and the skin surface temperature. Therefore the stated skin surface temperature of the subject device doesn't introduce any new issues of safety and effectiveness. |
| Size of Pouch | Approximately 10" x 16" (160 sq in) | 15.7" x 9.6" (151 sq in) | Similar – subject device is <0.5" larger. Slight change in size does not introduce any new issues of safety and effectiveness. |
| Sterility, Number of Uses | Non-sterile, Single Use, Disposable | Non-sterile, Single Use, Disposable | Same |

Bench Testing:

The following tests/evaluations were performed

- Temperature Profile Testing

- Temperature profile testing, including skin contact temperature, was performed on the International Biomedical InfaTherm™ Disposable Infant Warming Mattress and compared to the date from the predicate device. Testing included activation temperature testing, surface temperature, temperature duration testing and skin temperature. All tests were a pass.

- Stability Testing
  - Stability Testing was performed on the International Biomedical InfaTherm™ Disposable Infant Warming Mattress in conjunction with the temperature profile testing to confirm its shelf life of 20 months.

- Seal Strength Testing
  - The Subject device has been evaluated for seal strength testing of 80 psi pressure (pull test) for a cross seal and 50 Psi Pressure for an inline seal by the pouch manufacturer. The filled and sealed pouch is then subjected to a 40 pound for 15 minute burst test. We consider the burst and seal integrity testing to be safe and effective.

- Biocompatibility Testing
  - The biocompatibility evaluation for the International Biomedical InfaTherm™ Disposable Infant Warming Mattress was leveraged from k936084. Therefore, the evaluation is considered to be in accordance with the FDA guidance on Biocompatibility on the International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

Conclusion:

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate, the International Biomedical InfaTherm™ Disposable Infant Warming Mattress has been shown to be substantially equivalent to the predicate device identified, and does not present any new issues of safety or effectiveness