October 7, 2022

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

Re: K221154
Trade/Device Name: Infant Heel Warmer™; Heel Snuggler®
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot Or Cold Disposable Pack
Regulatory Class: Class I, reserved
Product Code: MPO
Dated: September 6, 2022
Received: September 6, 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 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)*
K221154

Device Name
Infant Heel Warmer™; Heel Snuggler®

Indications for Use *(Describe)*
The Infant Heel Warmer™; Heel Snuggler® are instant warm packs 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, nontoxic, non-sterile, disposable device. The Infant Heel Warmer™; Heel Snuggler® have two configurations, the Heel Snuggler®, which is designed to conform to the shape of the infant's heel, and the standard Infant Heel Warmer™. The devices are primarily used in hospitals, Doctor's offices, and other healthcare settings.

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.

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510(k) SUMMARY

Submitter Information:

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U.S.A.

Regulatory Affairs Contact:

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Date Summary Prepared: October 7, 2022

Device Identification:

Trade Names: Infant Heel Warmer™; Heel Snuggler®
Common Name: Infant Heel Warmer
Regulatory Class: I
Regulatory Name: Hot or cold disposable pack
Regulatory Number: (21 CFR 890.5710)
Product Code: MPO
510(k) number: K221154

Predicate Device:

CooperSurgical Inc. – Infant Heel Warmer (Model 24401), WarmGel® Infant Heel Warmer (Model 20418)– K151845

Reference Device:

Omni Therm Inc.– Omni Warm Gel Packs – K936084

Device Description:

The Infant Heel Warmer™/Heel Snuggler® 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, both models will reach between 104-107°F and then gradually decrease in temperature over time.

The Heel Snuggler® is a butterfly shape with two straps and the Infant Heel Warmer™ is rectangular with one strap. Straps with adhesive ends are attached to the packet for securing the heel warmer to the infant's foot, if desired. Immediately following activation of the packet, the user

rests the bottom of the infant's foot on one portion of the packet and holds the other 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. 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.

Indications for Use:

The Infant Heel Warmer™; Heel Snuggler® are instant warm packs 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, nontoxic, non-sterile, disposable device. The Infant Heel Warmer™; Heel Snuggler® have two configurations, the Heel Snuggler®, which is designed to conform to the shape of the infant's heel, and the standard Infant Heel Warmer™. The devices are primarily used in hospitals, Doctor's offices, and other healthcare settings.

Substantial Equivalence:

The substantial equivalence of the International Biomedical Infant Heel Warmer™; Heel Snuggler® 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 Infant Heel Warmer™; Heel Snuggler® K221154 Subject Device	CooperSurgical Inc. Infant Heel Warmer (Model 24401) WarmGel® Infant Heel Warmer (Model 20418)K151845 Predicate Device	Comparison
Indications for Use	The Infant Heel Warmer™; Heel Snuggler® are instant warm packs 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, nontoxic, non-sterile, disposable device. The Infant Heel Warmer™; Heel Snuggler® have two configurations, the Heel Snuggler®, which is designed to conform to the shape of the infant's heel, and the standard Infant Heel Warmer™. The devices are primarily used in hospitals, Doctor's offices, and other healthcare settings.	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, disposable warmer. The device is primarily used in hospitals, doctor's offices, and other healthcare facilities.	Similar – The subject device has two different shapes. The Slight Hour-glass shape of the subject device reduces the overall volume of the device, but the temperature characteristics are unaffected. The shape change allows the device to contour to the small patient foot. Therefore, the slight shape difference does not introduce any new issues of safety and effectiveness.
Environment of Use	Hospitals, doctor's offices and other healthcare settings.	Hospitals, doctor's offices, and other healthcare facilities.	Same
Prescriptive	Yes	Yes	Same
Pouch Material	Poly/nylon	Poly/nylon	Same
Solution Material	Sodium acetate (food grade) and water	Liquid version – Sodium acetate (food grade) and water Gel Version – Sodium Acetate (food grade), water, and hydroxyethylcellulose	Same (for the liquid version). The subject device does not offer a "Gel Version" like the predicate. Only offering the liquid version does not introduce any new issues of safety and effectiveness as it is merely reducing the number of products offered.
Activation Method	Flexing Disc	Flexing metal Disc	Same
Average Maximum Device Surface Temperature and Maximum Device	104-107°F	104°F, maximum peak 107°F	Same

surface Peak Temperature			
Average Skin Surface Temperature	102°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	5.5" x 3.5"	5" x 3.5"	Similar – subject device is 0.5" larger. Slight change in size does not introduce any new issues of safety and effectiveness.
Shape of Pouch (Heel Warmer)	Rectangular (Heel Warmer) Rectangular with Hour-glass cut out in center (Heel Snuggler)	Not Publicly Available	Similar – The Slight Hour-glass shape of the subject device reduces the overall volume of the device, but the temperature characteristics are unaffected. The shape change allows the device to contour to the small patient foot. Therefore, the slight shape difference does not introduce any new issues of safety and effectiveness.
Method of Attachment to Heel	Adhesive Strap	Adhesive Strap	Same
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 was performed on the International Biomedical Infant Heel Warmer™; Heel Snuggler® and compared to the data 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 Infant Heel Warmer™; Heel Snuggler® in conjunction with the temperature profile testing to confirm its shelf life of 24 months.

- Burst Testing
  - The Subject device has been evaluated for burst strength testing by using a 200 lb compression for 10 seconds. We consider the burst testing to be safe and effective.

- Biocompatibility Testing
  - The biocompatibility evaluation for the International Biomedical Infant Heel Warmer™; Heel Snuggler® 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 Infant Heel Warmer™ ; Heel Snuggler® has been shown to be substantially equivalent to the predicate device identified, and does not present any new issues of safety or effectiveness.