DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2016

CooperSurgical Inc.
c/o Roaida Johnson
Associate Director, New Product Development
95 Corporate Drive
Trumbull, CT 06611

Re: K151845
Trade/Device Name: Infant Heel Warmer (Model 24401) and
WarmGel Infant Heel Warmer (Model 20418)
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: Class I
Product Code: MPO
Dated: February 16, 2016
Received: February 17, 2016

Dear Ms. Johnson:

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. 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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151845

Device Name
Infant Heel Warmer (Model 24401)
WarmGel® Infant Heel Warmer (Model 20418)

Indications for Use *(Describe)*
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, non-sterile, disposable warmer.

The device is primarily used in hospitals, doctor's offices, and other healthcare facilities.

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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CooperSurgical

510(k) Summary
WarmGel® Infant Heel Warmer (Model 20418)
Infant Heel Warmer (Model 24401)

Submitter Information

Company Name: CooperSurgical Inc.
Company Address: 95 Corporate Drive
Trumbull, CT 06611
Telephone: 203-601-5200
Fax: 203-601-9870

Contact Person: Roaida Johnson

Date Prepared: March 17, 2016

Device Information

Trade Names: The Infant Heel Warmer (Model 24401)
WarmGel® Infant Heel Warmer (Model 20418)
Common Name: Infant Heel Warmer
Classification: Class I per 21 CFR 890.5710
Classification Name: Hot or cold disposable pack
Product Code: MPO

Predicate Device Information

The CooperSurgical Infant Heel Warmer is substantially equivalent to the following predicates:

Primary Predicate: Rapid Aid Instant Disposable Infant Heel Warmer – Disc (K150627)
Additional Predicate: DeRoyal Industries Infant Heel Warmer (K954716)

Device Description

The CooperSurgical Infant Heel Warmer, which is available in both a liquid version (The Infant Heel Warmer, Model 24401) and a gel version (WarmGel® Infant Heel Warmer, Model 20418), is a non-sterile, single-use, disposable device comprised of a biaxially oriented nylon (BON)/polyethylene outer pouch filled with a supersaturated solution of food grade sodium acetate and water (liquid version), or food grade sodium acetate, water, and hydroxyethylcellulose, a common thickener (gel version). An adhesive tape is attached to the pouch, which can hold the warmer in place if desired. The pouch also contains a stainless steel disc that, when flexed, initiates an exothermic crystallization of the sodium acetate, generating heat. When activated at $75^{o} + 1^{o}$ F, the maximum peak temperature of the CooperSurgical Infant Heel Warmer is 107^{o} F, which is reached in approximately 40 seconds and then gradually decreases over time.

Indications for Use

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.

Substantial Equivalence Analysis

The substantial equivalence of the CooperSurgical Infant Heel Warmer to the predicates 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 predicates.

Property	**Subject Device** **CooperSurgical Infant Heel Warmer**	**Primary Predicate** **Instant Disposable Infant Heel Warmer - Disc**	**Additional Predicate** **Infant Heel Warmer**	**Comparison**
Manufacturer	CooperSurgical Inc.	Rapid Aid Corp.	DeRoyal Industries	---
510(k) Number	K151845	K150627	K954716	---
Pouch Material	Poly/nylon	Poly/nylon	Unknown	Same as primary predicate
Solution Material	*Liquid version* - Sodium acetate (food grade) and water *Gel version* - Sodium acetate (food grade), water, and hydroxyethylcellulose	Sodium acetate (food grade) and water	Unknown	The hydroxyethylcellulose is a non-toxic thickening agent. The addition of the material does not raise new issues of safety and effectiveness.
Activation Method	Flexing metal disc	Flexing metal disc	Squeeze to burst inner pouch	Same as primary predicate
Average Maximum Temperature	104^{o} F	104^{o} F	105^{o} F	Same as primary predicate
Maximum Peak Temperature	107^{o} F	Unknown	Unknown	An animal study was performed to confirm no new issues of safety and effectiveness.
Size of Pouch	5" x 3.5"	5.5" x 3.75"	5" x 3.5"	Same as secondary predicate
Method of Attachment to Heel	Adhesive strap	Adhesive strap	Adhesive strap	Same as both predicates
Sterility, Number of Uses	Non-sterile, Single Use, Disposable	Non-sterile, Single Use, Disposable	Non-sterile, Single Use, Disposable	Same as both predicates

Non-Clinical Performance Testing

Temperature profile testing was performed on the CooperSurgical Infant Heel Warmer and on the predicate DeRoyal Infant Heel Warmer, and the results of this testing were used to determine the substantial equivalence of the Infant Heel Warmer to the predicate. For each sample, a calibrated thermocouple was attached to the center, the device was activated to allow the exothermic reaction to begin, and temperature readings were taken at 5 second intervals for 30 minutes. The samples were activated at a temperature of $75^{o} + 1^{o}$ F. The temperature profiles were compared between the CooperSurgical Infant Heel Warmer and the predicate DeRoyal Infant Heel Warmer, and were found to be equivalent.

Stability testing was also performed on the CooperSurgical Infant Heel Warmer to confirm its shelf life. Biocompatibility was performed on the patient-contacting components of the device (outer pouch and adhesive tape) per AAMI/ANSI/ISO 10993-5:2003, and AAMI/ANSI/ISO 10993-10:2010.

An animal study was performed to determine the temperature of the skin after application of the device. The study consisted of three light-skinned and three dark-skinned pigs, aged 3 to 3.5 weeks. A WarmGel Infant Heel Warmer was placed on one side of the animal while the opposite side served as a control. Temperatures were measured using thermocouples adhered to the animal, one under the heel warmer and one on the control side, at 1-minute intervals for a total of 22 minutes. The animals were then graded against established criteria for both thermal insult and erythema. There was no evidence of thermal injury in any of the animals, and all but one animal received an erythema score of 0, with the one animal receiving a score of 1, which is barely perceptible.

Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the CooperSurgical Infant Heel Warmer has been shown to be substantially equivalent to the predicate devices identified, and does not present any new issues of safety or effectiveness.