February 21, 2024

Care Essentials Pty Ltd
Abhay Sinha
Managing Director
103 Mornington Street
North Geelong, Victoria 3215
Australia

Re: K232502
Trade/Device Name: Cocoon Convective Warming System, Model CWS7000
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: September 14, 2023
Received: September 15, 2023

Dear Abhay Sinha:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eric E. Richardson -S

for Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K232502

Device Name
Cocoon Convective Warming System, Model CWS7000

Indications for Use *(Describe)*
The Cocoon Convective Warming System, Model CWS7000, is indicated for patient warming. The Cocoon Convective Warming Unit, Model CWS7000 has been designed for use with Cocoon Disposable Patient Warming Gown Blankets. It is intended for use with children, adolescent, and adult patients.

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.

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Cocoon™ Convective Warming System, Model CWS7000
Traditional 510(k) SUMMARY - K232502

Introduction

This summary is intended to comply with the requirements of SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant:	Abhay Sinha Care Essentials Pty. Ltd. 103 Mornington Street North Geelong Victoria, Australia 3215 Phone: +61-3-5277-1455 Email: queries@careessentials.com.au
510(k) Correspondent:	Abhay Sinha Care Essentials Pty. Ltd. 103 Mornington Street North Geelong Victoria, Australia 3215 Phone: +61-3-5277-1455 Email: queries@careessentials.com.au
Date of Summary:	21 February 2024
Type of 510(k) Submission:	Traditional
Device Trade or Proprietary Name:	Cocoon™ Convective Warming System, Model CWS7000
Common name:	Hypothermia System
Classification Name:	Thermal Regulating System
Product Code:	DWJ
Classification Panel:	Cardiovascular
Regulatory Class:	FDA Class II
Regulation #:	21 CFR §870.5900
Primary Predicate Device:	Bair Paws Temperature Management System K060865
Reference Device:	Cocoon Convective Warming System, K140635

Device Description

The Cocoon Convective Warming System, Model CWS7000 is part of the Cocoon family of temperature management systems that consists of portable forced-air temperature management units, Cocoon™ Disposable Patient Warming Gown Blanket.

The Cocoon Convective Warming System, Model CWS7000 comprises of the Cocoon Convective Warming Unit, Model CWS7000 unit and the Cocoon™ Disposable Patient Warming Gown Blankets. The Cocoon Convective Warming System, Model CWS7000 can be used in preoperative and postoperative settings. In a preoperative setting, the warming system provides prewarming and comfort warming. In a postoperative setting, the warming system provides comfort warming only. The Cocoon Convective warming system should be used by trained medical professionals only.

The Cocoon™ Convective Warming System, Model CWS7000 is not intended for use in the operating room.

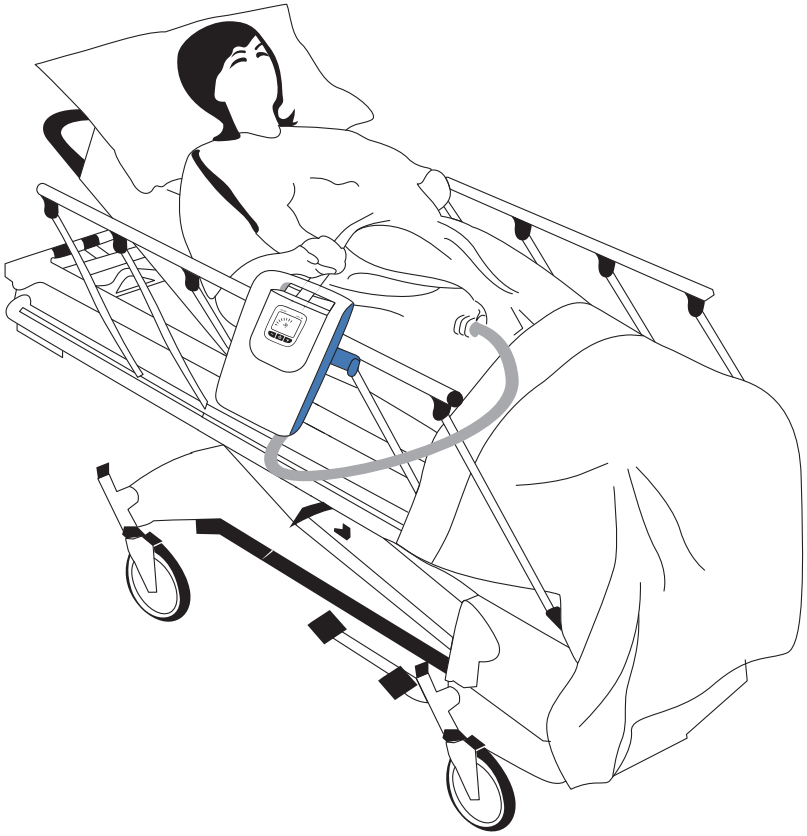

Figure 1. Cocoon™ Convective Warming System, Model CWS7000
Cocoon™ Convective Warming Unit, Model CWS7000 & Cocoon™ Disposable Patient Warming Gown Blanket

Cocoon™ Convective Warming Unit, Model CWS7000

The Cocoon Convective Warming Unit, Model CWS7000 is constituted of the following main components: a blower, a heating element, LCD screen and buttons for power and temperature controls. Warm air is delivered to the port of the Cocoon™ Disposable Patient Warming Gown Blanket through an insulated hose that is connected to the warming unit. The patient can adjust the air temperature and airflow using the temperature controller buttons located under the LCD screen of the warming unit. There is a power button also located under the LCD screen of the warming unit to turn the power ON/OFF.

The CWS7000 will not deliver air to the blanket below the ambient temperature of the room. Air is drawn into the rear of the CWS7000 and passes through a filter. There are multiple over-temperature prevention systems in place. In any specified temperature fault condition, the blower and heating element automatically shuts down and signals with audible tones or complete disconnect of power. The Cocoon Convective Warming Unit, Model CWS7000 continuously monitors system integrity and performance from the time of start-up.

Cocoon™ Warming Blanket

The Cocoon™ Disposable Patient Warming Gown Blanket has channels that deliver ambient or warm air through small perforations to warm the patient. The blankets enable pre-warming or post-warming comfort with a Cocoon CWS7000 warming unit or other Cocoon temperature management units. The Cocoon™ Disposable Patient Warming Gown Blanket is not made with natural rubber latex and are sized for children, adolescent, and adult patients.

Indications for Use

The Cocoon™ Convective Warming System, Model CWS7000, is indicated for patient warming. The Cocoon™ Convective Warming Unit, Model CWS7000 has been designed for use with Cocoon™ Disposable Patient Warming Gown Blankets. It is intended for use with children, adolescent, and adult patients.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	**Reference Device** Cocoon™ Convective Warming System K140635	**Primary Predicate Device** Bair Paws Temperature Management System K060865	Comparison Analysis
Manufacturer	Care Essentials Pty Ltd	Care Essentials Pty Ltd	3M Company	**N/A**
510(k) Reference	K232502	K140635	K060865	**N/A**
Trade Name	Cocoon™ Convective Warming System, Model CWS7000	Cocoon™ Convective Warming System	Bair Paws Temperature Management System	**N/A**
Common name	Hypothermia System	Hypothermia System	Hypothermia System	**Same**
Regulation Number	21 CFR §870.5900	21 CFR §870.5900	21 CFR §870.5900	**Same**
Class	FDA Class II	FDA Class II	FDA Class II	**Same**
Product Code	DWJ	DWJ	DWJ	**Same**
Indications for Use	The Cocoon™ Convective Warming System, Model CWS7000, is indicated for patient warming. The Cocoon™ Convective Warming Unit, Model CWS7000 has been designed for use with Cocoon™ Disposable Patient Warming Gown Blankets. It is intended for use with children, adolescent, and adult patients.	The Cocoon Convective Warming System is indicated for hyper or hypothermic patients or normothermic patients for whom induced hyper or hypothermia or localized temperature therapy is clinically indicated. In addition, the Cocoon Convective Warming System can be used to provide patient thermal comfort when conditions exist that may cause patients to become too cold or too warm. The Cocoon Convective Warming System can be used with adult and pediatric patients.	The Bair Hugger temperature management system is indicated for hyper – or hypothermic patients or normothermic patients for whom induced hyper – or hypothermia or localized temperature therapy is clinically indicated. In Addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold.	**Similar**
Areas for device use	Pre-op, intensive care unit, labor and delivery, recovery room, emergency rooms, long-term care facilities and other areas	Pre-op, intensive care unit, operating room, labor and delivery, recovery room, emergency rooms, long-term care facilities	Pre-op, intensive care unit, labor and delivery, recovery room, emergency rooms, ships, aircraft, EMT vehicles, accident	**Similar**

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	**Reference Device** Cocoon™ Convective Warming System K140635	**Primary Predicate Device** Bair Paws Temperature Management System K060865	Comparison Analysis
	where medical professionals can warm patients.	and other areas where medical professionals can warm patients.	sites, long-term care facilities, home health care and other areas where medical professionals can warm patients.	
Intended patient population	Children, adolescent and adult patients	Adult and pediatric patients	Adult and pediatric patients	**Similar**
Patient position	Stationary	Stationary	Stationary	**Same**
Device positioning	Can be set on table, shelf, or other hard surface; clamped on an I.V pole; or hung on a bed rail.	Can be set on table, shelf, or other hard surface; clamped on an I.V pole; or hung on a bed rail.	Can be set on table, shelf, or other hard surface; clamped on an I.V pole; or hung on a bed rail; or attached to the wall using a wall mount bracket.	**Similar**
Dimensions	33.5 cm x 24.5 cm x 10.4 cm (Height * Width * Depth)	40 cm x 29 cm x 22 cm (Height * Width * Depth)	27.9 cm x 19.6 cm x 6.4 cm (Height * Width * Depth)	**Similar**
Weight	Max.: 3 kg	Max.: 6 kg	Max.: 3 kg	**Similar**
Method of operation	The Cocoon™ Convective Warming System, Model CWS7000 has a blower motor and a heating element. The warming unit delivers warmed air through a hose that is connected to a port in the Cocoon™ warming blanket	The Cocoon™ Convective Warming System has a blower motor and a heating element. The warming unit delivers warmed air through a hose that is connected to a port in the Cocoon™ warming blanket	The Bair Paws Temperature Management system has a blower motor and a heating element. The warming unit delivers warmed air through a hose that is connected to a port in the Bair Paws warming gown.	**Same**
Alarm system	Over-temperature detection, color indicator light illuminates, heater and blower shuts down.	Over-temperature detection, color indicator light illuminates, heater and blower shuts down.	Over-temperature detection, color indicator light illuminates, heater and blower shuts down.	**Same**
Materials	Plastic/Metal	Plastic/Metal	Plastic/Metal	**Same**
Warming Unit hose	Detachable, flexible, fixed length (2m), washable, 2.0” diameter	Detachable, flexible, fixed length (1.8m), washable, 2.5” diameter	Detachable, flexible, fixed length, washable, 1.5” diameter	**Similar**

TABLE 2: SUMMARY OF NONCLINICAL TESTING

Number/Code	Title	Version	Pass/Fail
AAMI/ANSI ES60601-1	Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Edition 3.1; FDA rec. # 19-46)	2005/(R)2012 & A1:2012, C1:2009/ (R)2012 & A2:2010/(R)2012/ A2:2021	Pass
IEC 60601-1-2	Medical electrical equipment - Part 1-2: Collateral Standard: Electromagnetic Compatibility - Requirements and tests (Edition 4.1; FDA rec. # 19-36)	2014/A1:2021	Pass
IEC 62304	Medical Device Software - Software Life Cycle Processes (Edition 1.1; FDA rec. # 13-79)	2006/A1:2016	Pass
IEC 60601-2-35	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use. (Edition 2.0; FDA rec. # 6-483)	2020	Pass
ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process (Edition 5.0; FDA rec. # 2-258)	2018	Pass
ISO 14971	Medical devices - Application of risk management to medical devices (Edition 3.0; FDA rec. # 5-125)	2019	Meets requirements

Summary of Clinical Testing

Clinical testing is not applicable to the Cocoon™ Convective Warming System, Model CWS7000.

Conclusion

The conclusions drawn from the comparison of technological characteristics demonstrate that the Cocoon™ Convective Warming System, Model CWS7000, is substantially equivalent to the legally marketed Bair Paws Temperature Management System (K060865).