510(k) Summary

JUL 2 5 2014

Introduction

This summary is intended to comply with requirements of the 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

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510(k) Correspondent

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Date Prepared

03 March 2014

Device Trade or Proprietary Name

Cocoon Convective Warming System

Common Name

Hypothermia System

Classification Name

Thermal Regulating System

Device Class

FDA Class II

Product Code

DWJ

Regulation Number

21 CFR 870.5900

Predicate Device(s)

The Cocoon Convective Warming System is substantially equivalent to the following predicate device(s):

- K053645 Bair Hugger Temperature Management System Model 750.
- K041686 Bair Hugger Temperature Management System Model 505.

Device Description

The Cocoon Convective Warming system incorporates the Convective Warming Machine CWS4000, and the Cocoon Disposable Patient Warming Blankets. The Convective Warming Machine is a mains-powered, microprocessor-controlled device that delivers a continuous flow of temperature-controlled air through a flexible hose to the warming blanket. The temperature of the air delivered to the blanket can be set to one of six settings: Ambient, 34°C, 37°C, 40°C, 43°C, or 46°C. When a temperature of 46°C is selected, the setting automatically drops to 43°C after 10 minutes.

Intended Use

The Cocoon Convective Warming System is indicated for hyper or hypothermic patients or normothermic patients for who 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.

Clinical Testing

Care Essentials Pty Ltd did not conduct a clinical study as defined in the guidance for Industry Financial Disclosures by Clinical Investigators to determine substantial equivalence. Care Essentials Pty Ltd conducted performance testing with satisfactory results. In addition the device have been CE Marked and included in the Australian Register of Therapeutic Goods for more than 5 years.

Non-Clinical Testing

Non-clinical testing was performed in order to validate the design against the company's specified design requirements, and to assure conformance with the following voluntary standards:

- ANSI/AAMI/ES60601-1(2005 + C1 + A2) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3). (General).
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. (Biocompatibility).

- ISO 14971:2007 Medical devices - Application of risk management to medical devices. (General).

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program according to standard ISO 14971.

Substantial Equivalence

Care Essentials Pty Ltd believes that the Cocoon Convective Warming System is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

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

July 25, 2014

Care Essentials Pty Ltd
Abhay Sinha
Managing Director
25 Slevin Street
North Geelong Vic 3215
Australia

Re: K140635
Trade/Device Name: Cocoon Convective Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: June 23, 2014
Received: June 25, 2014

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 (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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140635

Device Name: Cocoon Convective Warming System

Indications for Use:

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.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)