K123083

COVIDIEN

APR 17 2013

510(k) Summary

Date Summary Prepared: 28-September-2012
Date Summary Revised: 20-November-2012

510(k) Submitter / Holder

Covidien llc
6135 Gunbarrel Avenue
Boulder, CO 80301

Contact

Name: Stacey A. Strand
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Name of Device

Trade Name: WarmTouch™ Convective Warming Unit
Catalog Number: 5016000
Common Name: Thermal Regulating System
Classification Name: Cardiovascular (21 CFR § 870.5900, Class II, DWJ)

Purpose of Submission

The purpose of this submission is to introduce the Covidien WarmTouch™ Convective Warming Unit which effectively provides a means for treating or preventing hypothermia in adult and pediatric patients in clinical settings. The design and intended use of the WarmTouch™ Convective Warming Unit Warming Unit is fundamentally similar to the predicate device. The new WarmTouch™ Convective Warming Unit includes modifications of the: hardware interface to a Graphic User Interface (GUI), blower's design for compliance with the IEC 80601-2-35:2009 (2nd edition) standard, Printed Circuit Board Assembly (PCBA) to comply with the European Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU.

This submission followed the "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, 2005," the "Guidance for Industry on General / Specific Intended Use, 1998," and the "Draft Guidance for Industry and FDA Staff: Factors to Consider when Making Benefit-Risk Determinations in Medical Device Premarket Review, 2011."

Predicate Device

The WarmTouch™ Convective Warming Unit Warming Unit was compared and found to be substantially equivalent to the following product of comparable type in commercial distribution:

Trade Name:	WarmTouch™ Model 5300A Patient Warming System
Device Common Name:	Thermal Regulating System
510(k) Number:	K020604 (cleared April 2002)
Manufacturer:	Covidien, formerly Nellcor Puritan Bennett, a division of Tyco Healthcare

This WarmTouch™ Convective Warming Unit Warming Unit 510(k) submission is the only initial premarket notification for this new blower unit. There have not been any prior 510(k) premarket notification submissions, regarding this new blower unit, withdrawn or deleted.

Device Description

The WarmTouch™ Convective Warming Unit is an electro-mechanical blower that delivers heated air. The WarmTouch™ Convective Warming Unit is part of the WarmTouch™ Convective Warming System that consists of the blower warming unit and Covidien's WarmTouch™ Blankets. The blower actively delivers heated air from the blower's flexible hose to a lightweight blanket. During this process, the blanket has already been draped over the patient's body, before the blanket begins distributing the heated air through numerous small perforations in the blanket, which allows the air to reach the targeted areas of the patient's body.

Indications for Use

The WarmTouch Convective Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia, and for the management of appropriate normothermia.

Intended Use

The WarmTouch™ Convective Warming Unit is a portable device that is used in conjunction with a WarmTouch™ Blanket as a system that is intended for prescription use. The warming unit regulated the management of normothermia from pre-operative to post-operative, which aligns with the Intended Use of the currently cleared (predicate) device. There are no clinical implications, no new diagnostic or therapeutic information that is not normally associated with other general uses of the device, nor are there any additional outcomes that could influence patient management.

Technological and Performance Characteristics

The design technology of the proposed and predicate blower units have the same method of operation, power control, temperature sensor, materials, manufacturing method, and accessories. The main design technology differences between the proposed and predicate blower units are the control mechanism, motor, and user interface.

Performance Data

The design of the WarmTouch™ Convective Warming Unit features the same ambient blower operating range and air flow rate as the predicate device. The proposed blower unit alarms have improved accuracy, along with the improved performance of air temperature exiting the blower.

Design verification and validation testing was performed to confirm the blower unit's mechanical and software features met specified requirements. All verification and validation activities met product requirements.

Animal testing was not required to demonstrate that the proposed device met its design requirements.

Usability / Human Factors

Usability was evaluated with users in simulated operating environments. These studies consisted of formative and summative studies, which demonstrate the device provides adequate assurance of safety and performance (in regards to human factors/usability aspects) for the patient and operator.

Substantial Equivalence

In establishing substantial equivalence of the WarmTouch™ Convective Warming Unit with the predicate device, Covidien evaluated the intended use, indications for use, and technological characteristics. The use of the WarmTouch™ Convective Warming Unit in patient monitoring environments does not raise any new types of questions of safety and effectiveness compared with the predicate device that is currently in use.

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

April 17, 2013

Covidien
c/o Ms. Stacey Strand
6135 Gunbarrel Avenue
Boulder, CO 80301

Re: K123083
Trade/Device Name: WarmTouch Convective Warming Unit
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: February 15, 2013
Received: February 19, 2013

Dear Ms. Strand:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Matthew G. Hillebrenner

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 Statement

510(k) Number (if known): K123083

Device Name:

Covidien WarmTouch™ Convective Warming System

Indications for Use:

The WarmTouch Convective Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia, and for the management of appropriate normothermia.

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)

Matthew G. Hillebrenner