K121720

AUG 20 2012

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	WElkins, LLC
DATE PREPARED:	3 August 2012
CONTACT PERSON:	Christopher Blodgett 1430 Blue Oaks Blvd., Suite 250 Roseville, CA 95747 Phone: 207.449.6398 Fax: 866.663.2271 Email: christopher@welkinsmed.com
TRADE NAME:	WElkins EMT/ICU Temperature Management System
CLASSIFICATION NAME:	Thermal Regulating System
DEVICE CLASSIFICATION:	Class II
REGULATION NUMBER:	870.5900
PRODUCT CODE:	DWJ
PREDICATE DEVICES:	Cincinnati SubZero Blanketrol II (K110104) Medivance Arctic Sun 5000 (K101092) MedCool RapidCool (K070112) EMCOOLS EMCOOLSpad (K100071)

Substantially Equivalent To:

The WElkins EMT/ICU Temperature Management System is substantially equivalent in intended use, Principle of operation and technological characteristics to the Cincinnati SubZero Blanketrol II (K110104), Medivance Arctic Sun 5000 (K101092), MedCool RapidCool (K070112), and the EMCOOLS EMCOOLSpad (K100071).

Description of the Device Subject to Premarket Notification:

The WElkins EMT/ICU Temperature Management System is a thermoregulatory device that reduces and/or maintains patient body temperature within a range of 30°C (86°F) to 37°C (98.6°F). The System delivers temperature-controlled coolant ranging between 5°C (41°F) and 25°C (77°F) from one of two Conditioning Units (EMT or ICU) to a patient-contacting Cooling Pad, resulting in heat exchange between the coolant and the patient.

The EMT Conditioning Unit is a lightweight, battery-powered pack for use in the field; patient temperature is controlled manually, by modulating the temperature of coolant circulated to the Cooling Pad, and must be monitored regularly during treatment. The

ICU Conditioning Unit is an enhanced, microprocessor-driven version of the EMT Conditioning Unit designed for use in the hospital setting; it features a touchscreen graphical user interface and automatic patient temperature control, in addition to the same core hydraulic and pneumatic cooling system used in the EMT Conditioning Unit. A patient temperature probe connected to the ICU Conditioning Unit provides biofeedback to an internal control algorithm, which automatically modulates coolant temperature to achieve a patient target temperature determined by the clinician.

The Cooling Pad comes in Universal and Head-Neck configurations. The safety and effectiveness of the Cooling Pad has not been demonstrated for treatment of stroke or head trauma, and is not indicated for use in their treatment.

Indication for Use:

The WElkins EMT Temperature Management System is a thermal regulating system, indicated for temperature reduction in patients where clinically indicated.

The WElkins ICU Temperature Management System is a thermal regulating system, indicated for temperature reduction in patients where clinically indicated and monitoring of patient temperature.

Technological Characteristics:

The WElkins EMT/ICU Temperature Management System has the same technological characteristics and is similar in overall design, materials and configuration compared to the predicate device. It is substantially equivalent to the predicate in terms of:

- Indications for Use
- Basic design/configuration
- Where used
- Target population
- Cooling method

Testing and Performance Data:

- Biocompatibility
- Electromagnetic Compatibility
- Electrical Safety
- Functional Performance

Basis for Determination of Substantial Equivalence:

Upon reviewing and comparing intended use, design, materials, principle of operation and overall technological characteristics, the WElkins EMT/ICU Temperature Management System is determined by WElkins, LLC to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 20 2012

Welkins, LLC.
c/o Mr. Mark Job
1394 25th Street NW
Buffalo MN 55313

Re: K121720
Trade/Device Name: Welkins EMT/ICU Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: June 11, 2012
Received: June 12, 2012

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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: K121720

Device Name: WElkins EMT/ICU Temperature Management System

Indications for Use: The WElkins EMT Temperature Management System is a thermal regulating system, indicated for temperature reduction in patients where clinically indicated.

The WElkins ICU Temperature Management System is a thermal regulating system, indicated for temperature reduction in patients where clinically indicated and monitoring of patient temperature.

OR

Prescription Use __X___ (Per 21 CFR 801 Subpart D)

Over-The-Counter Use_____ (Per 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121720