K100092

510k Summary per 21 CFR 807.92 (c)

OCT 12 2010

Submitted by / Contact Data

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Date prepared:	October 2009 – August 2010

Device Name

Trade Name:	EMCOOLSpad
Common/Usual Name:	Hypothermia System
Classification Name:	System/Thermal Regulating (per 21 CFR 870.5900)
Product Code	NZE

Predicate Devices

No	Model	Producer	510(k)
1	**Arctic Sun® Model 2000** Temperature Management System	**Medivance, Inc.** 321 South Taylor Ave., Suite 200 Louisville, Colorado	K010338
2	**Thermosuit™** Hypothermia System	**Life Recovery Systems HD** 150 Hopper Avenue, Waldwick, New Jersey	K061023

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Device Description

The EMCOOLSpad is a single use surface (skin) cooling device, which is adherent to the patien´s skin and so highly adjustable during the cooling procedure.

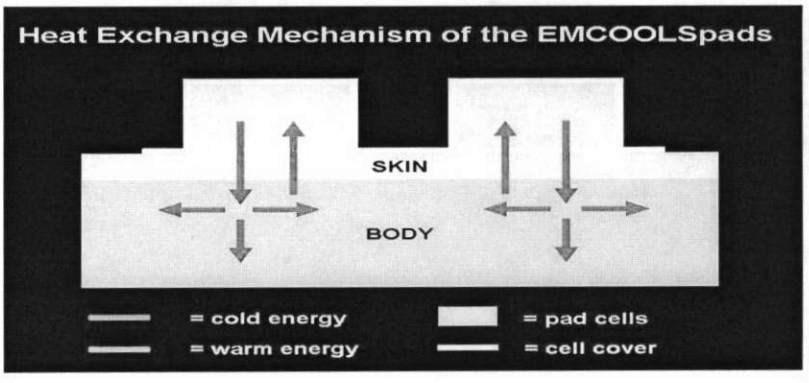
An EMCOOLSpad consists of multiple cooling-cells made of thermoplastic polyurethane, filled with high thermal conductivity material, stored frozen at 0 to -10°C.

Physics and Mechanism Summary

In nature there is always an automatically started balancing-process among interacting subjects, this process stops automatically when a perfectly balanced energy level is reached.

For the EMCOOLSpad and the patient this interaction process is started automatically when the pads are adhered to the skin (see sketch below) and ends automatically with a balanced energy level between cold pad and warm skin.

If you remove EMCOOLSpads from the patient´s body, another balancing-process commences automatically, leading to a slow and mild re-warming, again to a certain "balanced level".



Between start-point and end-point of this balancing process, the cold goes into the skin vertically and locally first, but immediately is "transported" away into the complete human body and cools it down. Seen from the patient´s perspective the warmth of the body and skin is "transported" into the pad and melts it.

User and Patient Interface

The patient's core temperature is regulated within in a certain temperature range by manually removing (= warming) or applying (=cooling) the EMCOOLSpads.

Device Interface

A commercially available third-party temperature probe connected to a commercially available third-party monitor senses the patient's core temperature.

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Intended Use of the Device

Temperature reduction for adult patients where clinically indicated, e.g. in hyperthermic patients.

Summary of the technological characteristics of the device compared to the predicate device

Device → / **Criteria ↓**	Arctic Sun® K010338	EMCOOLSpad	Thermosuit™ K061023
Thermal regulating system	Yes	Yes	Yes
Non-invasive system	Yes	Yes	Yes
Patient surface cooling	Yes	Yes	Yes
Permanent contact to the patient's skin during cooling	Yes	Yes	Yes
Temperature gradient between patient and cooling pad/blanket	Yes	Yes	Yes
Removal of thermal energy from the patient	Yes	Yes	Yes
Rapid cooling function	Yes	Yes	Yes
temperature monitoring with a temperature probe (own brand or 3rd party)	Yes	Yes	Yes
Rewarming function	Yes	No	No

The EMCOOLSpad and the identified predicate devices are all non-invasive, thermal regulating systems for patient surface cooling under permanent contact to the patients´skin during cooling targeting the removal of thermal energy from the patient.

The technical realization how to cool down a patient might be differently solved, but the features and functional criteria above make all devices substantially equivalent.

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Testing

Biocompatibility Testing was performed according to these standards:

ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing; 2003

ISO 10993-5: 1999-11; Biological evaluation of medical devices – Part 5: Tests for cytotoxicity; in vitro methods.

prEN ISO 10993-5: 2007, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-10; Biological evaluation of medical devices – Part 10 Test for irritation and delayed hypersensitivity (components).

ISO 10993 -12: 2008 -02, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials.

The tests were conducted by Medical Device Services – Dr. Rossberger GmbH, Lilienthalstraße 4, 82205 Gilching, Germany (www.mdservices.de) acc. to Directive 93/43/EEC, 90/385/EEC, EN ISO/IEC 17025 (ZLG-P-870.96.08 accredited) and Good Laboratory Practices (GLP).

Performance Testing – Bench

Lab testing was done internally by Research & Development to benchmark the EMCOOLSpad and the predicate devices.
No difference between the EMCOOLSpad and the ArcticSun could be detected in terms of the cooling-rate. The EMCOOLSpad does cool down not as aggressively as seen for the very fast cooling-rate of the ThermoSuit, so we conclude it is physiologically even better tolerated.

Performance Testing – Animal

Animal testing was done by qualified and trained physicians and nurses to demonstrate the "under-the-pad" skin safety of the EMCOOLSpad on pigs after 24h and 1 week. Both for the immediate assessment of potential damages (24h) and for the assessment of potential damages developing over time (1 week), not any skin damage could be detected on the large amount of pig skin photos recorded. So we conclude it is safe to use it in terms of skin safety.

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Conclusion

The comparison of the EMCOOLSpad and the predicate devices resulted -based on functional criteria- in the conclusion that the EMCOOLSpad is substantially equivalent to the predicate devices.

Based upon the biocompatibility- and performance-testing we conclude that the EMCOOLSpad temperature reduction system performs as intended and raises no new safety or effectiveness issues.

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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

OCT 12 2010

EMCOOLS – Emergency Medical Cooling Systems AG
c/o Ms. Kristen Langen
MHS- Foreign Affairs
TUV SUD America, Inc
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

Re: K100071
Trade/Device Name: EMCOOLSpad
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: NZE
Dated: September 3, 2010
Received: September 9, 2010

Dear Ms. Langen:

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,

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

Enclosure

4. Indication for Use

510(k) Number (if known): K100071

Device Name: EMCOOLSpad

Indication For Use: Temperature reduction in adult patients where clinically indicated, e.g. in hyperthermic patients.

Prescription Use YES (21 CFR Part 801 Subpart D) And/Or Over the Counter Use NO (21 CFR Part 801 Subpart C)

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K100071