K070112

JUL 13 2007

510(k) Summary for the *RapidCool*™ Patient Temperature Management System

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

1. General Information

Submitter:	MedCool Incorporated 30 Washington Street Wellesley, Massachusetts 02481
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864
Summary Preparation Date:	January 9, 2007

2. Names

Device Name:	*RapidCool*™ Patient Temperature Management System
Classification Name:	Thermal Regulating System Product Code: DWJ

3. Predicate Devices

The *RapidCool* Patient Temperature Management System is substantially equivalent to a combination of the Life Recovery Systems ThermoSuit System (K061023) and the Cincinnati Sub Zero Blanketrol (K811742).

4. Device Description

The *RapidCool*™ Patient Temperature Management System reduces, and/or maintains patient body temperature at a desired level by removing heat from a patient's body. The major components of the *RapidCool* system consist of a Control Console, body surface cooling appliances, tubing sets, and an esophageal temperature sensor. The body surface cooling appliances consist of a back cooling pad, a right axilla-cooling pad, a neck cooling pad, and a head-cooling cap. The control console supplies cold water to the surface cooling appliances, and controls the operation of the system. Tubing sets connect the control console to the surface

cooling appliances. The esophageal temperature sensor is connected to the control console and is used to display and patient body temperature.

Body temperature can be reduced and/or maintained in a temperature range between 32 to 37 degrees centigrade by a thermostatic control feature of the control console. The operator can select the desired body temperature within this range.

5. Indications for Use

The *RapidCool* Patient Temperature Management System is a thermal regulating system indicated for temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients, and monitoring of patient temperature.

6. Performance Data

Performance data was submitted which demonstrated that the system performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

MedCool, Inc.
c/o Ms. Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K070112
RapidCool™ Patient Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: June 25, 2007
Received: June 28, 2007

Dear Ms. O'Connell:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochner

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): K070112

Device Name: *RapidCool*™ Patient Temperature Management System

Indications For Use:

The *RapidCool*™ Patient Temperature Management System is a thermal regulating system indicated for temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients, and monitoring of patient temperature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bahner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070112