OCT 2 3 2003

K030421 1/3

6 510K Summary

510(k) SUMMARY FOR ALSIUS CORPORTATION'S COOLGARD AND CATHETER THERMAL REGULATION SYSTEM

Submitter's Name, Address, Telephone Number, and Contact Person:

ALSIUS CORPORATION
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Name of Device:

The Alsius CoolGard And Catheter Thermal Regulation System.

Common or Usual Name:

Central Venous Catheter (short term) and Thermal Regulating System.

Classification Name:

Venous heat exchange catheters and associated temperature control systems have not been specifically classified by the FDA. However, FDA has classified venous catheters and thermal regulating systems as Class II devices under 21 C.F.R. §§ 880.5200 and §§ 870.5900 respectively.

Predicate Device:

Cardiac Surgery	K012512 SetPoint® Endovascular Temperature Management system. Radiant Medical, Inc., Redwood City CA
Neurosurgery	K022366 Celsius® Endovascular Temperature Management system. Innercool Therapies Inc, San Diego CA

Indications for Use

The COOLGARD™ 3000/Alsius Catheter Thermal Regulation System, using either the Icy™ or Fortius™ model catheter, is indicated for use:

- **in cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care, and,**
- **to induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.**

Technical Characteristics:

The CoolGard and Catheter Thermal Regulation System consists of the CoolGard™ 3000, a disposable Start Up Kit used in the CoolGard™ for interface with the cooling bath and patient catheter and the Intravascular Catheter. The Alsius CoolGard™ 3000 is an integrated electro-mechanical heater/cooler that consists of a temperature monitor, a temperature controller unit, a heat exchanger unit, and roller pump. It supplies temperature controlled sterile saline to the indwelling Catheter that is placed percutaneously in the patient.

The technical characteristics of the Catheter are essentially identical to those of widely used multi-lumen central venous catheters except for the dedicated closed loop fluid path through the heat exchange balloons. The Alsius Catheter materials are all biocompatible polyurethanes.

Likewise, the CoolGard™ 3000 heater/cooler has the same technical features as the medical heater/cooler unit Identified as the predicate device. These common technical features include connections for recirculating coolant to and intravascular catheter and all or combinations of the following: redundant safety controls and alarms, patient monitoring and control and temperature displays for the clinician users.

Two Models of Intravascular catheters are available for use with the CoolGard and Catheter Thermal Regulation System:

1. ICY™ Catheter Kit Model IC-3585A
2. Fortius™ Catheter Kit Model FR-5093A

The ICY™ and Fortius™ catheters are multi lumen intravascular catheters in various sizes. Two of the catheter's lumens are used to circulate sterile saline to exchange heat with the central venous blood supply. When the heat exchange feature of the catheter is in use, heated/chilled saline is pumped through the heat exchange lumen, expanding the diameter of the distal portion of the catheter to a nominal 5mm where the heating/cooling membranes interface with the patient's circulating blood. The inflow lumen/outflow lumen forms a closed-loop system through which the heated/chilled saline circulates. The chilled saline is not infused into the patient.

Additional lumens of the Alsius Catheters consist of a standard guide wire lumen that can be used as a primary infusion lumen, and a second infusion lumen within the shaft, depending on the catheter model selected by the clinician.

The Catheter blood contact surfaces are coated with Duraflo® Treatment, a heparin coating manufactured by Edwards Lifesciences Corporation.

The Alsius Catheters are supplied sterile for single-use only.

Principles of Operation:

The CoolGard™ 3000 system automatically adjusts the temperature of the heater/chiller saline bath to achieve the patient target temperature that has previously been set by the attending physician. This is done via data from a temperature probe in the patient that interfaces with the temperature controller. This principle of operation is identical to currently marketed devices.

Summary of the Basis for Finding of Substantial Equivalence:

The CoolGard and Catheter Thermal Regulation System indication statement and intended use is identical to the predicate device. Principle of operation is the same as the predicate device. The technical characteristics and materials used are very similar to the predicate device.

Conclusion

In summary, descriptive information and performance data demonstrate that the Alsius CoolGard and Catheter Thermal Regulation System characteristics do not raise new questions of safety and effectiveness. Where appropriate, performance data demonstrate equivalence. The CoolGard and Catheter Thermal Regulation System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2003

Ken Collins, M.D.
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15770 Laguna Canyon Road, Suite 150
Irvine, California 92618

Re: K030421
Trade/Device Name: CoolGard and Catheter Thermal Regulation System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: NCX
Dated: August 8, 2003
Received: August 11, 2003

Dear Dr. Collins:

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.

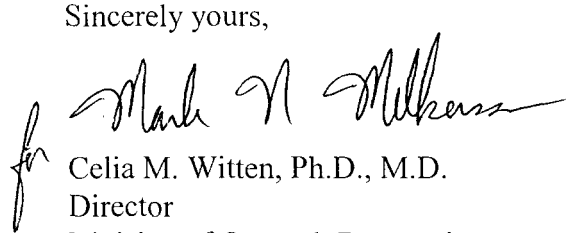
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k)Number(if known): K030421

Device Name: CoolGard and Catheter Thermal Regulation System

Indications for Use

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- **to induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.**

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030421

Prescription Use ☒ Over the Counter ☐