5 510(k) Summary or 510(k) Statement

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

FDA has classified the Alsius CoolGard 3000/Alsius heat exchange catheters as Class II devices under 21 C.F.R. §§ 870.5900 - System, Hypothermia, Intravenous, Cooling. Classification Product Code: NCX.

Predicate Devices

The product acts as its own predicate. This is a modification to the software of the device.

Indications for Use

The following Indications for Use have clearance within the USA. The COOLGARD™ 3000 can be used with any of the Alsius Catheters. The indications for use are specific to the catheter. Please refer to the Indications for Use statement in the catheter specific Instructions for Use.

Indications for Use *(K030421, K051912, K052443)*

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.

Indications for Use *(K014241, K051912)*

The Alsius CoolGard® 3000 and Cool Line™ Catheter Thermal Regulation System is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

Table 1-1. Mortality by Diagnosis (ITT)

	Cool Line			Control			
	n	N	%	n	N	%	p-value*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the results of this study please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill Stroke Patient" #101416-001.

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 identical to the predicate device with the exception of revisions to the software that controls the device.

The following models of Intravascular catheters are available for use with the CoolGard and Catheter Thermal Regulation System:

1. ICY® Catheter Kit Model IC-3585A(CO)

2. ICY® Catheter Kit Model IC-3893A(CO)
3. Fortius® Catheter Kit Model FR-5093B(CO)
4. Cool Line® Catheter Kit Model CL 2085B(CO)
5. Cool Line® Catheter Kit Model CL 2295A(CO)

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 the predicate device.

Summary of the Basis for Finding of Substantial Equivalence

The System in this premarket notification acts as its own predicate. There are no changes to the indications for use of the device. Revisions have been made to the software of the device for which supportive evidence is provided to establish that there are no new questions of safety or efficacy.

The System is substantially equivalent to the predicate device, the system itself.

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 system in this revision acts as its own predicate device. The CoolGard and Catheter Thermal Regulation System is safe and effective when used in accordance with the Directions For Use and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2006

Alsius Corporation
c/o Kenneth A. Collins, M.D.
Executive Vice President
15770 Laguna Canyon Road, Suite 150
Irvine, California 92618

Re: K060308
Trade/Device Name: Alsius CoolGard 3000 and Catheter Thermal Regulation System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: NCX
Dated: February 2, 2006
Received: February 9, 2006

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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that the Cool Line Catheter will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling as a box warning immediately following the indications for use statement: The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI, cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

Mortality by Diagnosis (ITT)

	Cool Line			Control			
	n	N	%	n	N	%	p-value*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the results of this study please refer to Physician's Manual – "Normothermia for the Neuro-critically ill stroke patient" #101416-001.

Please note that the above labeling limitation is required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before this limitation is modified in any way or removed from the device's labeling. This limitation does not apply to the Icy & Fortius Catheters.

The FDA finding of substantial equivalence of your device to a legally marked predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification: (21 CFR 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/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060308

Device Name: Alsius CoolGard 3000 and Catheter Thermal Regulation System

Indications For Use:

Indications For Use:

Cool Line Cathers - Indications for Use:

The Alsius CoolGard® 3000 and Cool Line ™ Catheter Thermal Regulation System is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarrachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarrachnoid hemorrhage).

Mortality by Diagnosis (ITT analysis)

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the clinical trial results please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient" #101416-001.

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)

Indications for Use

510(k) Number (if known): K060308

Device Name: Alsius CoolGard 3000 and Catheter Thermal Regulation System

Indications For Use:

Fortius and Icy Catheters - 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.

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)