K033623 1/2

MAY 21 2004

510(k) SUMMARY

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

Submitted by

INNERCOOL *therapies*, Inc.
3931 Sorrento Valley Boulevard
San Diego, California 92121
Telephone: (858) 713-9507
Contact: Steve Reitzler, Vice President, Regulatory Affairs & Quality Assurance
Date Prepared: September 26, 2003

Device Name

Trade or Proprietary Name:	*Celsius Control™ System*
Common or Usual Name:	Thermal Regulating System
Classification Name:	Thermal Regulating System

Predicate Devices

The subject device is substantially equivalent, in whole or in part, to predicate devices manufactured by Radiant Medical (K012512), and Alsius (K014241, K030421).

Device Description

The subject device is a thermal regulating system consisting of three (3) parts:

- an endovascular catheter having a heat exchange element at the distal end, through which a thermal transfer fluid is circulated to cool or warm the blood, and which is available in various diameters from 9 french to 14 french;
- a console containing refrigeration/heating elements, a heat exchanger to cool and warm the circulating fluid, a pump to circulate that fluid, and controls and software necessary to operate the system; and

- a sterile tubing set to connect the console to the catheter, and through which the heat transfer fluid is circulated to and from the catheter in a closed-loop manner.

Two (2) models of the System are available: One which uses conventional, off-the-shelf thermistor probes such as YSI-400 esophageal probes, to monitor patient temperature and control System operation, and one that uses a thermistor integral to the catheter.

Intended Use

The Celsius Control™ System is a thermal regulating system intended to induce, maintain and reverse mild hypothermia in neurosurgical patients in surgery and in recovery/intensive care, to achieve and/or maintain normothermia in cardiac surgery patients in surgery and in recovery/ intensive care, and for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who required 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. A randomized controlled study of endovascular cooling in patients with subarachnoid hemorrhage and primary traumatic brain injury has shown increased mortality as compared to patients receiving standard of care.

Comparison to Predicate Devices

The subject device has the same, or equivalent, indications for use as do other thermal regulating systems cleared for commercial distribution in the U.S.;

The subject device has the same or equivalent design characteristics as other thermal regulating systems cleared for commercial distribution in the U.S.;

The subject device is composed of biocompatible materials meeting the requirements of ISO 10993-1, as are other devices cleared for commercial distribution in the U.S.;

The subject device has equivalent performance in inducing and reversing hypothermia, and in maintaining normothermia, as do other thermal regulating systems commercially available in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2004

Mr. Steve Reitzler
Vice President, Regulatory Affairs
and Quality Assurance
INNERCOOL Therapies, Inc.
3931 Sorrento Valley Boulevard
San Diego, California 92121

Re: K033623
Trade/Device Name: Celsius Control System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX
Dated: February 19, 2004
Received: February 23, 2004

Dear Mr. Reitzler:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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 this device 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:

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. A randomized controlled study of endovascular cooling in patients with subarrachnoid hemorrhage and primary traumatic brain injury has shown increased mortality as compared to patients receiving standard of care.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed 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 (301) 594-4659. 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/dsma/dsmamain.html.

Sincerely yours,

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

Enclosure

5.0 DRAFT LABELING

5.1 Indications for Use

510(k) Number (if known): K033623

Device Name: INNERCOOL *therapies*, Inc., ***Celsius Control™ System***

Indications for Use:

"The Celsius Control™ System is a thermal regulating system intended to induce, maintain and reverse mild hypothermia in neurosurgical patients in surgery and in recovery/intensive care, to achieve and/or maintain normothermia in cardiac surgery patients in surgery and in recovery/ intensive care, and for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who required access to the central venous circulation and who are intubated and sedated."

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

510(k) Number K033623

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)