K080905

OCT 17 2008

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.

6740 Top Gun Road

San Diego, California 92121

Telephone: (858) 677-6390

Contact: Jennifer Spinella, Vice President, Regulatory Affairs & Quality Assurance

Date Prepared: February 15, 2008

Device Name

Trade or Proprietary Name: RapidBlue™ 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 INNERCOOL *therapies* (K033623).

Device Description

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

1. 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.

2. A sterile cassette 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.

3. 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 10.7 french to 14 french.

The modified system offers a mode, which uses conventional, off-the-shelf temperature probes such as YSI-400 esophageal probes, to monitor patient temperature and control system operation, and one mode that uses an integrated temperature sensor in the catheter.

Intended Use

The RapidBlue™ 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.

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

OCT 17 2008

Innercool Therapies, Inc.
% Ms. Jennifer Spinella
VP, Regulatory Affairs and Quality Assurance
6740 Top Gun Street
San Diego, California 92121

Re: K080908
Trade/Device Name: RapidBlue™ System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system.
Regulatory Class: II
Product Code: NCX
Dated: August 08, 2008
Received: August 11, 2008

Dear Ms. Spinella:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.1 Indications for Use

510(k) Number (if known): K080908

Device Name: INNERCOOL *therapies*, Inc., ***RapidBlue™ System***

Indications for Use:

*"The **RapidBlue™ 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."*

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Neil R Ogden for mac

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

510(k) Number K080908