DEC 17 1997

510(K) SUMMARY

TRADE NAME:
Thermo-STAT System

GENERIC NAME:
Body Core Thermoregulation System

CLASSIFICATION OF PERFORMANCE STANDARD:
The Food and Drug Administration has classified devices of this generic type into Class II, DWJ. To date, no performance standards have been established for devices of this type.

INTENDED USE:
The Thermo-STAT is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and a thermal load (heat) to a distal appendage.

DEVICE DESCRIPTION:
The Thermo-STAT is a non-invasive and portable body core warming device which provides a non-invasive technique to treat and prevent hypothermia. The Thermo-STAT's principle of action for counteracting hypothermia is to create a thermal pipeline between the skin and the body core. The Thermo-STAT functions by applying a combination of heat and pressure to only the distal aspect of an arm or leg. Using the Thermo-STAT, a thermal load is exchanged between the application site and the body core. Vasoconstriction in a hypothermic individual prevents superficial heat alone from effectively altering the body core temperature. The Thermo-STAT circumvents this "vasoconstrictive blockade" with a slight negative pressure (40-60mmHg) and enables a thermal load to be transferred directly and exclusively from a thermal heat pad to the body core via the bloodstream. Current means, such as forced air rewarming, fail to effectively overcome the "vasoconstrictive blockade."

PERFORMANCE DATA:
Sample devices were subjected to physical bench testing. Tests included current vacuum and heat cycle test, flow rate capabilities, and performance under simulated conditions. Based on these test results, it was concluded that the design and proper fabrication of that design offered a considerable safety margin with regard to simulated clinical use.

HUMAN CLINICAL EVALUATION:

A clinical study was performed under a non-significant risk IDE to test and confirm the system's functionality and safety during non-invasive active rewarming of the body core temperature for hypothermic patients. A clinical evaluation was randomly performed on 22 patients undergoing a variety of general surgical procedures. These patients were observed hypothermic at the conclusion of their surgery and, therefore, the Thermo-STAT was employed to raise their body core temperature. The combination of negative pressure and thermal load was non-invasively applied to hypothermic patients' distal limb with their informed consent. A 2°C rise in body core temperature was observed in the first 10 minutes of application of the Thermo-STAT device. It was observed that there were no side effects to the patient from this treatment. The clinical tests resulted in the conclusion that negative pressure rewarming is a viable technique for rapidly rewarming patients in the PACU.

BIOCOMPATIBILITY TESTS OF MATERIALS:

Tests for biocompatibility of materials used in the fabrication of the Thermo-STAT were performed to establish that the materials used in the device meet the qualifications for short-term use non-invasively on the skin's surface. As a result of these tests, it was concluded that the materials met the qualifications for short term use non-invasively on the skin's surface.

STERILIZATION:

The Thermo-STAT is designed to be a non-sterile product.

PACKAGING:

The Thermo-STAT (seal and thermal fluid pad) is for single-use only and will be placed in a protective dispenser. A protective overshipper will be utilized for shipping.

Packaging was designed to protect the device from damage during processing, storage and distribution.

SUBSTANTIAL EQUIVALENCE:

The Thermo-STAT is equivalent in its intended use, as well as design, composition and function, to the rewarming devices legally marketed by Augustine Medical, MityVac and Prism Technologies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

Mr. W. Jeffrey Chandler
President and CEO
Aquarius Medical Corporation
16099 North 82nd Street
Suite B-1
Scottsdale, AZ 85260

DEC 17 1997

Re: K970367
Thermo-STAT™ System
Regulatory Class: II (Two)
Product Code: DWJ
Dated: September 26, 1997
Received: September 26, 1997

Dear Mr. Chandler:

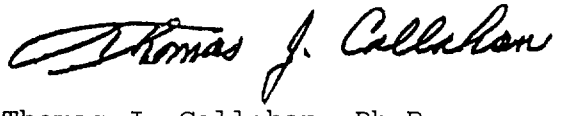
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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. 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970367

Device Name: *Thermo-STAT*™ System

Indication for Use: The Thermo-STAT is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and a thermal load (heat) to a distal appendage.

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

Concurrence of DCRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970367

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)