K070342

Supporting Clinical Engineering Worldwide

510(k) Summary

MAR 19 2007

Submitter Information:

American IV Products, Inc.
7485 Shipley Avenue
Harmans, MD 21077

Contact:

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Director of Engineering
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Date Prepared:

February 5, 2007

Product Name:

Classification Name: Clinical Electronic Thermometer
Common Name: Clinical Electronic Thermometer
Proprietary Name: Clinical Electronic Thermometer

Predicate Device:

These AIV devices are Substantially equivalent to the following legally marketed devices:

Critikon Company : K992638, K874378

P/N – 8813 & 8814

Alaris Medical Systems: K050230, K955846, K860436

P/N – 2885, 2886, 2887, 2888, 3880L, 3882L

Description:

AIV's Clinical Electronic Thermometers (also referred to as Temperature Probes) are replacement thermometers for temperature monitoring/measuring systems. The device is reusable. The devices are electronic thermometers using a thermistor as the temperature sensor. The devices are placed inside a protective sheath (not manufactured or supplied by AIV). Then the thermometer is used on the patient by trained medical personnel. The signal of the sensor is displayed on a monitor/measuring system (not manufactured or supplied by AIV).

The probe consists of a thermistor located in a metal tipped plastic shaft. The shaft is attached to a plastic body that allows the protective sheath (not supplied component that actually touches the patient) to be gripped and ejected off the probe. A shielded multi-conductor cable is used to conduct thermistor signals to the connector for the monitor/measuring system. Some probes have a heating resistor that allows a more rapid temperature measurement.

The AIV Temperature Probes use the same type of construction and have the same technological characteristics as the predicate devices.

The Temperature Probes are limited by the indications for use of the connected monitoring or measuring equipment.

Intended Use:

The devices are intended to be used in a clinical setting, physicians' offices or other alternate care settings. The device is intended for the quantitative detection of body temperature, which can be obtained orally, under the arm (axially) or rectally by trained medical personnel.

Comparison to Predicate Device:

	AIV	Critikon	Alaris Medical Systems
Intended Use	for the quantitative detection of body temperature, which can be obtained orally, under the arm (axially) or rectally	Same	Same
Patient Usage	Reusable.	Same	Same
Technical Characteristics	Thermistor technology	Same	Same
Design/Appearance	Probe with shaft and body assembly that uses a protective sheath	Same	Same
Type of Construction	Thermistor in metal tipped plastic shaft, flexible, shielded, multi conductor electrical cable and monitor connector.	Same	Same
Connector Design	Connectors are selected to fit the appropriate monitors	Same	Same
Cable Length	Various specified lengths.	Same	Same
Wire Material	Braided shield, tin/copper with elastomer jacket.	Same	Same
Sterility	Used non-sterile.	Same	Same

Performance Data and Conclusions:

- AIV design is equivalent to predicate device design.
- Bench Testing demonstrates that the AIV devices perform as intended.
- These devices do not raise new issues of safety and effectiveness, nor do they alter the fundamental technology of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

Mr. John Taylor
Director of Engineering &
Acting Head of Regulatory Affairs
American I.V. Products, Incorporated
7485 Shipley Avenue
Harmans, Maryland 21077

Re: K070342
Trade/Device Name: Clinical Electronic Thermometer, Models TP11403 to TP11413
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 5, 2007
Received: February 6, 2007

Dear Mr. Taylor:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070342

Device Name: Clinical Electronic Thermometer

Indications For Use:

The devices are intended to be used in a clinical setting, physicians' offices or other alternate care settings. The devices are reusable and are intended for the quantitative detection of body temperature, which can be obtained orally, under the arm (axially) or rectally by trained medical personnel.

AIV Part #	Temperature Monitor/Display
TP11403	Critikon Dinamap Pro 200/400, Cardinal Health Vital Check (IVAC) Series 4400 & 4500, Criticare Vital Care 506
TP11404	Critikon Dinamap Pro 200/400, Cardinal Health Vital Check (IVAC) Series 4400 & 4500, Criticare Vital Care 506
TP11405	Alaris TurboTemp 2180CX01EE & 2180C
TP11406	Alaris TurboTemp 2180CX01EE
TP11407	Alaris TurboTemp 2185BX01EE & 2185B
TP11408	Alaris TurboTemp 2185BX01EE
TP11409	Critikon Dinamap 8100T
TP11410	Critikon Dinamap 8100T
TP11411	Critikon Dinamap XL and 9300 Series
TP11412	Critikon Dinamap XL and 9300 Series
TP11413	Critikon Dinamap XL and 9300 Series

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)

[signature]

[illegible] General Hospital,
[illegible] Devices

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