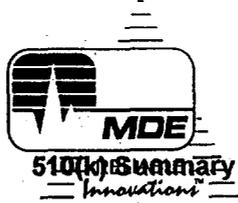


K970011

JUL - 9 1997

**ESCORT® II**  
**CLINICAL THERMOMETRY MODULE**  
**510(K) SUBMISSION**  
**510(K) SUMMARY**



K970011

**ESCORT® II Clinical Thermometry Module**

**Submitted by:**

David M. Trueblood  
Regulatory Affairs Manager  
Medical Data Electronics  
12720 Wentworth Street  
Arleta, California 91331

Telephone: 818-768-6411  
Contact: David M. Trueblood

**Date Prepared:** December 31, 1996

**Device Name:**

**Trade Name:** ESCORT® II Clinical Thermometry Module (CTM)

**Common/Usual Name:** Thermometer, Electronic Thermometer, Predictive Thermometer

**Classification Name:** Thermometer, Electronic, Clinical

**Substantial Equivalence:**

The Clinical Thermometry Module (CTM) for the ESCORT® II Patient Monitor is substantially equivalent to the ESCORT II Patient Monitor with Yellow Springs Instruments (YSI) temperature measurement capability, to the Diatek® SureTemp® Thermometer System and to the Welch Allyn LifeSign® Critical Vital Signs Monitor (CVSM). The MDE Clinical Thermometry Module has the same intended use, has the same or equivalent design, materials, method of action and labeling and, therefore, is substantially equivalent to these and other clinical electronic thermometers currently distributed commercially in the United States. Temperature channels are factory-configured, as are all parameters contained in the MDE Multiparameter Module (MPM). Since hardware, software and function are identical in the CTM to those incorporated in the MPM, the CVSM and in the SureTemp®, which have all been previously granted marketing clearance by FDA, substantial equivalence to these devices is assured and claimed.

**Device Description:**

The CTM consists of an elongated metal heat-conductive probe connected to the multiparameter module (MPM) which may be used with the ESCORT® II Patient Monitor through a coiled cable. The probe contains a thermistor which conveys temperature information to the MPM for calculation of patient temperature which may be displayed on the ESCORT® II display panel.

Prior to use, the probe is inserted into a plastic probe cover. The cover offers no significant barrier to heat transfer from the patient to the probe body. The disposable nature of the probe cover prevents microbiological cross-contamination among patients such as might occur with a reusable probe.

Calculation of patient temperature may, in the normal mode, utilize algorithms which enable accurate temperature prediction within 3 to 10 seconds of probe placement.

**Intended Use:**

The Clinical Thermometry Module is intended to be used for the intermittent determination of temperature in hypothermic, normothermic, or febrile children or adults. In the Normal mode, oral use in compliant patients allowing maintenance of the probe in the sublingual pocket for the temperature-taking cycle, enables the predictive algorithm to determine an accurate temperature in approximately 4 seconds. Rectal use results in a predictive temperature in approximately 10 seconds.

**Comparison to Predicate Devices:**

The Clinical Thermometry Module for use with the ESCORT II Patient Monitor is shown to demonstrate substantial equivalence to the ESCORT II Patient Monitor with YSI temperature measurement technology, to the Diatek® SureTemp® Thermometer System and the Welch Allyn LifeSign® Critical Vital Signs Monitor (CVSM).

The following table summarizes the characteristics of the four electronic thermometers.

ITEM	CTM	CTM WITH YSI	SURETEMP®	LIFESIGN®
Display Temperature Range	84.0°F to 108.8°F 28.9°C to 42.2°C	20° to 50°C	84.0 to 108.8°F 28.9 to 42.2°C	84.0 to 108.8°F 28.9 to 42.2°C
Laboratory Accuracy	±0.2°F, in Monitor mode in a stirred water bath	±0.1°C	±0.2°F, in Monitor mode in a stirred water bath	per ASTM E-1112-86
Precision	0.1°F 0.1°C	Not Specified	0.1°F 0.1°C	Not Specified
Operating Temperature Range	60.8°F to 104°F 16°C to 40°C	5°C to 40°C	60.8°F to 104°F 16°C to 40°C	82°F to 104°F 10°C to 40°C
Operating Humidity Range	15% to 95%, non-condensing	0 to 90%, non-condensing	15% to 95%, non-condensing	15% to 90%, non-condensing
Storage Temperature Range	-4°F to 120° F -20°C to 50°C	-40°C to +70°C	-4°F to 120° F -20°C to 50°C	-4°F to 122° F -20°C to 50°C
Storage Humidity Range	15% to 95%, non-condensing	10 to 100%, non-condensing	15% to 95%, non-condensing	15% to 90%, non-condensing
Power Source	Modular Batteries; 2 each, 12V, 2.3 AH AC Main: 115/230VAC, Selectable 48-62 Hz, Autosensing	Modular Batteries; 2 each, 12V, 2.3 AH AC Main: 115/230VAC, Selectable 48-62 Hz, Autosensing	AA, Alkaline	Lead Acid
	AC Current: 0.4A @ 115VAC 0.2 A @ 230VAC	AC Current: 0.4A @ 115VAC 0.2 A @ 230VAC	N/A	AC Current: 120 VAC 220-240 VAC
Battery Operating Life	2.5 to 4 hours, depending on monitor configuration	2.5 to 4 hours, depending on monitor configuration	About 6000 readings	10 Hours, minimum

**Device Testing:**

Bench testing methods were utilized to confirm the accuracy and repeatability of the as referenced to the predicate devices containing the Diatek clinical electronic thermometer technology. The intent of the bench tests was: 1.) To exercise the CTM by making temperature measurements at operational environmental extremes of temperature and humidity to ensure system performance comparable to the predicate devices incorporating Diatek technology and, 2.) To validate the CTM against the predicate devices incorporating Diatek technology using a constant temperature source.

Results of statistical analysis of the bench test data are contained in the following tables.

Simple Linear Regression Analysis:					
Slope:	0.995	r:	0.999	Mean Error:	0.000
Y-Intercept:	0.0938	SEE:	0.5246	Std. Deviation:	0.0391
Environmental Test Data					

Simple Linear Regression Analysis:					
Slope:	1.000	r:	1.000	Mean Error:	0.000
Y-Intercept:	0.000	SEE:	0.000	Std. Deviation:	0.000
Heat Well Test Data					

**Conclusions of Bench Tests:**

Results of bench testing confirm the accuracy of the CTM relative to two predicate devices utilizing the same proprietary technology. The results support the substantial equivalence claim for the CTM.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. David M. Trueblood  
Regulatory Affairs Manager  
Medical Data Electronics, Incorporated  
12720 Wentworth Street  
Arleta, California 91331

JUL - 9 1997

Re: K970011  
Trade Name: Escort II Clinical Thermometry Module (CTM)  
Regulatory Class: II  
Product Code: FLL  
Dated: April 9, 1997  
Received: April 10, 1997

Dear Mr. Trueblood:

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 (Pre-market 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 requirement, 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

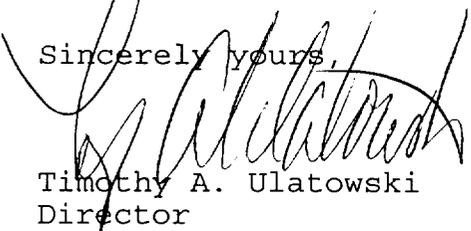
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K970011

Device Name: ESCORT II CLINICAL THERMOMETRY MODULE (CIM)

Indications for Use: The primary use of the CIM, as an intermittent thermometer, is to take a patient's temperature at a single point in time. However, the instrument's Monitor mode also allows continuous monitoring of the patient's temperature. The CIM is a clinical grade thermometer. It is intended for use by healthcare practitioners only; typically in a hospital, clinic or mobile environment. It is not intended for lay or home use.

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

Concurrence of CORH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Patricia Crivello*  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K970011

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

{Optional Format 1-2-96}