

K970086

AUG 25 1997

Date: _____

By: _____

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SAFETY AND EFFECTIVENESS SUMMARY

*This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Company Name: Kentec Medical, Inc.

Contact Person: Matt Wilken

Common or usual name of device Reusable Temperature Sensor (probe)

Trade or proprietary name Accutemp-Probe

pc 020 of 7/21/97.

Classification name (if known) Class II ~~as~~ as required by 21 CFR.94

Predicate device(s) to which substantial equivalence is being claimed Air Shields/Ohmeda

Device Description

1. Brief explanation of how the device functions.

There are two modes of operation for temperature control in incubators and infant warmers where these products are used, air or manual mode and baby or skin temperature control mode.

When operating in the air or manual mode, the skin temperature probe may be used just to monitor the patient's skin temperature. Here, a nurse would control the heater output manually.

When operating in the "Baby" or "Skin Temperature Control Mode" the warming units controller utilizes the skin temperature to automatically adjust the heater output of the unit to maintain a pre-selected skin temperature.

2. Basic scientific concepts that form the basis for the device.

The thermistor tip which gets taped to the infant is made of a material whose resistance to electrical flow changes when the tip materials temperature changes. Two small wires run from the plug end at the incubator or warmer to the thermistor tip. One wire to each side.

A very small current goes to the tip and depending on how warm the tip is has to do with how much current returns via the other wire to the plug. That current is computed into temperatures.

3. Significant physical and performance characteristics of the device.
(Ex. device design and physical properties.)

These products fit the Steinhart-Hart equation which is the standard for describing thermistor curves.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Matt Wilken
Official Correspondent
Kentec Medical, Incorporated
17871 Fitch
Irvine, California 92714

AUG 25 1997

Re: K970686
Trade Name: Accutemp-Probe
Regulatory Class: II
Product Code: FMT
Dated: May 28, 1997
Received: May 30, 1997

Dear Mr. Wilken:

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:

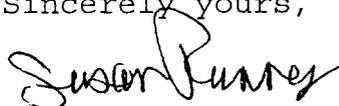
Page 2 - Mr. Wilken

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) 594-4618. 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,



Dr. 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): K970686

Device Name: ACCUTEMP - PROBE

REUSABLE SKIN TEMPERATURE SENSORS

Indications For Use:

There are two modes of operation for temperature control in incubators and infant warmers where these products are used, air or manual mode and baby or skin temperature control mode.

When operating in the air or manual mode, a skin temperature probe may be used just to monitor the patient's skin temperature. Here, a nurse would control the heater output manually.

When operating in the "Baby" or "Skin Temperature Control Mode" the warming units controller utilizes the skin temperature probe, connected between the controller and the infant, to automatically adjust the heater output of the unit to maintain a pre-selected skin temperature.

This product looks like and has identical indications for use as the disposable products we now sell under 510(k) # 960080, issued May 1, 1996.

This product differs only in its durability. It uses heavier wire and a disc type tip (which primarily identifies it as a reusable unit.)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K970686

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____