K033790

JUN - 3 2004

Research, development and production of electronic and electromedical equipments
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510(k) Summary

Submitter:	Tecnimed srl
Address:	12, P.le Cocchi 21040 Vedano Olona (VA) Italy
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E-mail:	info@tecnimed.it
Contact:	Francesco Bellifemine
Date of Summary:	October 19th, 2003
Trade name:	Thermofocus 0800 series, Thermofocus 0900 series, Thermofocus 01500 series, Thermofocus 0700 series.
Classification:	Class II Panel 80 Medical specialty: General Hospital Procode: FFL – Clinical Electronic Thermometer Regulation number: 880.2910
Predicate Device:	TemporalScanner thermometer, formerly known as SensorTouch (K011291) made by Exergen Corporation – Watertown – MA 02172

Device Description:

Thermofocus devices belonging to the 0800, 0900, 01500, 0700 series are hand-held and battery-operated, taking skin temperature mainly in the middle of the forehead. In case of difficult to take the temperature on this area it is also possible to take the temperature on the navel or under the armpit.
The Thermofocus devices use the principle of surveying the natural emission of infrared thermal radiation from all objects, including the human body.
Thanks to an exclusive optic aiming system, the peculiarity of Thermofocus thermometers is to take the temperature at distance, without any contact with the patient.

Intended Use:

Thermofocus 0800, 0900, 01500, 0700 series are infrared thermometers intended for the intermittent measurement of human body temperature in people of all ages.

Characteristics:

The Thermofocus thermometers and the predicate device are used to measure the temperature of human body by means of a thermopile sensor.
To show the temperature in the LCD display, both devices make a mathematical adjustment. Thermopile and thermistor sensors generate two signals that are necessary to make the mathematical adjustment.

Both devices meet the ASTM E1965-98 *Standard for Infrared Thermometer for Intermittent Determination of Patient Temperature*, as far as this standard applies to them.

SensorTouch is a skin surface contact thermometer, while Thermofocus is a non-contact thermometer detecting body temperature at an established distance that is indicated by a led aiming system.
Sensor Touch can only display the familiar rectal temperature, while Thermofocus can select the reference temperature between oral and rectal ones.

Summary of non-clinical Performance Testing:

Performance test	Results
Accuracy tests	Pass
Repetability tests	Pass
°F vs °C tests	Pass
Error messages tests	Pass
Display limits tests	Pass
DFU evaluation	Pass
Current leakage tests	Pass
Variable voltage tests	Pass
EMC tests	Pass

Summary of clinical Performance Testing:

The numerous tests conducted in our laboratories and also in hospital and clinics, on several subjects and at several ambient temperatures, demonstrate a substantial equivalence between Thermofocus and the predicate Sensortouch.

Conclusion:

Since performance tests are similar, and both thermometers have the same basic characteristics and conform to the same standard, we can conclude that Thermofocus devices belonging to the 0800, 0900, 01500, 0700 series are substantially equivalent to the predicate Sensortouch.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2004

Tecnimed S.R.L.
C/O Ms. Carolann Kotula
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K033790
Trade/Device Name: Thermofocus Professional 0800 Series,
Thermofocus 0900 Series, Thermofocus 01500 Series, Thermofocus 0700 Series
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 28, 2004
Received: April 29, 2004

Dear Ms. Kotula:

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.

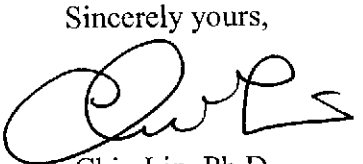
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indication of Use

510(k) Number (if known): K033790

Device Name: Thermofocus professional_0800 series, Thermofocus 0900 series, Thermofocus 01500 series, Thermofocus 0700 series.

Indications for Use:
The Thermofocus series 0800, 0900, 01500 and 0700 are infrared thermometers intended for the intermittent measurement of human body temperature of people of all ages

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✓ Over-the-Counter ___ Prescription

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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