2/12/99

K983887

510(k) Summary

Medisim Ltd.

Up-Grade Electrical Thermometer

510(k) Number K_____

Applicant's Name:

Medisim Ltd.
The Technology Park Manhat
Jerusalem 38900, Israel
Tel: 972-2-679-9204
Fax: 972-2-679-9198

Contact Person:

Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth St, NW
Washington, DC 20004
Tel: (202) 637-5794
Fax: (202) 637-5910

Date Prepared: November 2, 1998

Trade Name:

Up-Grade Electrical Thermometer

Classification Name:

Clinical Electronic Thermometer

Common Name:

Electronic Thermometer

Classification:

Clinical Electronic Thermometers are class II devices (product code 80 FLL) and are reviewed by the General Hospital Division.

Indication for Use:

The **Up-Grade** is an over-the-counter, non-sterile, reusable clinical thermometer intended for the determination of oral, rectal and axillary body temperature determination in humans.

Predicate Device:

The **Up-Grade** is substantially equivalent to Diatek Instruments, Inc.'s SureTemp™ Thermometer System, (K964643) and Becton Dickinson and Company's B-D Flexible Thermometer (K902624).

Device Description:

The **Up-Grade** is a compact predictive clinical thermometer designed to measure human body temperature by detecting heat from three different body sites: axilla, rectum and mouth, by using the heat conduction principle and prediction. The device is designed to calculate the maximum temperature of probe tip in contact with the body site, without waiting for thermal equilibrium to occur, by heat transfer data and mathematical algorithm. The temperature reading range is from 35.5°C to 42.0°C (95.5°F to 107.6°F) and the time of measurement varies between 4 to 6 seconds.

Non-Clinical and Clinical Tests Performed for Determination of Substantial Equivalence:

The **Up-Grade** Electrical Thermometer conforms with the following voluntary standards: ASTM E1112 and IEC 601-1. Additionally, the safety and efficacy performance of the device has been non-clinically and clinically established through comparative testing with market-cleared devices.

Conclusion:

Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that the over-the-counter **Up-Grade** Electrical Thermometer is substantially equivalent to its predicate devices and the device does not raise new questions of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Medisim Ltd.
C/O Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K983887
Trade Name: Up-Grade
Regulatory Class: II
Product Code: FLL
Dated: December 28, 1998
Received: December 28, 1998

Dear Mr. Kahan

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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):_____

Device Name: Up-Grade Electrical Thermometer

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983887

(Optional Format 1-2-96)