

**SECTION 6 - SUMMARY OF SAFETY AND EFFECTIVENESS**

SEP - 1 2005

---

(Premarket Notification [510(k)] Number)

**1. Applicant**

Medisim Ltd.  
Kenes International Bldg.  
2a Hayarden St.  
Airport City, 70151 ISRAEL  
Tel: +972-3-9795560-4  
Fax: +972-3-9795565

**Corresponding Official:**

Name: Ahava M. Stein, Consultant  
Address: A. Stein - Regulatory Affairs Consulting  
Beit Hapa'amon (Box 124)  
20 Hata'as St.  
44425 Kfar Saba  
ISRAEL  
Tel: +972-9-767 0002  
Fax: +972-9-766 8534

|                                       |  |
|---------------------------------------|--|
| <b>2. Device Name:</b>                | Dual Mode Up-Grade Forehead/ Underarm<br>Thermometer                             |
| <b>Device trade/proprietary name:</b> | Dual Mode Up-Grade Forehead/ Underarm<br>Thermometer (a.k.a. FHT2, UGFT-2, UGDM) |
| <b>Common Name:</b>                   | Electronic Thermometer   |
| <b>Classification Name:</b>           | Electronic Clinical Thermometer, Class II, 880.2910                              |

K051422/51  
2 of 2

### 3. Predicate Devices

The Dual Mode Up-Grade Forehead/ Underarm Thermometer is substantially equivalent to the following devices:

| Device                        | Manufacturer | 510(k) No. |
|-------------------------------|--------------|------------|
| Up-Grade Forehead Thermometer | Medisim Ltd. | K032362    |
| M5T Instant Fever Thermometer | Medisim Ltd. | K012217    |

### 4. Intended Use

The Dual Mode Up-Grade Forehead/ Underarm Thermometer device is intended for determination of body temperature.

### 5. Description of the Device

The Dual Mode Up-Grade Forehead/ Underarm Thermometer is a clinical electronic thermometer used for determination of body temperature. The over-the-counter Dual Mode Up-Grade Forehead/ Underarm Thermometer is designed to calculate the maximum temperature of a probe 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 35.0°C to 42.0°C (95.5°F to 107.6°F) and the time of measurement is 6-10 seconds.

### 6. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the Dual Mode Up-Grade Forehead/ Underarm Thermometer device are substantially equivalent to the predicate devices cited above.



SEP - 1 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medisim Limited  
C/O Ms. Ahava M. Stein  
Regulatory Affairs Consultant  
Beit Hapa `amon Box 124  
20 Hata'as St.  
44425 Kfar Saba  
ISRAEL 44225

Re: K051422

Trade/Device Name: Dual Mode Up-Grade ForeHead/Underarm Thermometer Device  
Regulation Number: 21 CFR 880.2910  
Regulation Name: Clinical Electronic Thermometer  
Regulatory Class: II  
Product Code: FLL  
Dated: August 17, 2005  
Received: August 24, 2005

Dear Ms. Stein:

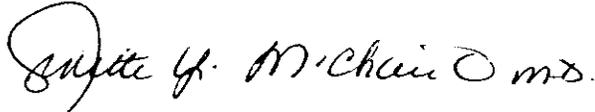
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 443-6597 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

K051422/31  
1 of 1

Indications for Use Statement

Page 1 of 1

510(k) Number (if known): \_\_\_\_\_

Device Name: Dual Mode Up-Grade Forehead/ Underarm Thermometer device

Indications for use: The Dual Mode Up-Grade Forehead/ Underarm Thermometer device is a non-sterile, reusable clinical thermometer intended for the determination of human's body temperature using the forehead and axilla as measurement sites..

Prescription Use \_\_\_\_\_  
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use ✓  
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

 For ADW  
Per CSC

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

510(k) Number: K051422