K070590

SEP 1 1 2007

EXHIBIT #1a

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____

1. Submitter's Identification:

   Microlife Intellectual Property GmbH, Switzerland
   Espenstrasse 139
   9443 Widnau / Switzerland
   Date Summary Prepared: February 22, 2007

2. Name of the Device:
   Microlife Instant Digital Electronic Thermometer, Model MT19S1R

3. Predicate Device Information:
   Microlife Instant Digital Electronic Thermometer, Model MT1811, K#04310.

4. Device Description:

   This Instant Digital Electronic Thermometer enables very fast and reliable measurements and with its predicative technology the thermometer offers a very high clinical accuracy and has been designed to provide a maximum of user-friendliness.

   The basic principle of this thermometer's that change of thermistor resistance, caused by changes of temperature, are converted to changes of frequency of RC oscillator circuit, Therefore, temperature can be given by measuring the frequency of oscillator.

5. Intended Use:

   Microlife MT1 951 R Instant Digital Electronic Thermometer is used for the intermittent measurement and monitoring of oral human body temperature. The intended use of this thermometer is for ages 18 months and above.

K070590

6. Comparison to Predicate Devices:

The Microlife Instant Digital Electronic Thermometer, Model MT1 951 R is substantially equivalent to Microlife Instant Digital Electronic Thermometer, Model MTI8I1, K#043110 which has the similar intended use and is similar in design to the predicate device.

The Microlife Instant Digital Electronic Thermometer MT1 9S1R and the predicate device are identical in the temperature measurements algorithm and fundamental scientific technology. They mainly differ in the "Try again" function. When abnormal action is detected, the thermometer will stop playing the melody and displaV'---~ and hear "Try again" speaking. The subject device also differs from the predicate device in measuring location, melody Great Job, curve probe tip and shape. In all, these differences do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology, therefore, they are substantial equivalent.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM £1112, as well as 1EC60601-1 and 1EC60601-I-2 requirements.

Guidance documents included the FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers.

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted using the Microlife Instant Digital Electronic Thermometer, Model MT1 951 R. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Microlife Clinical Test Protocol outline.

9. Conclusions:

The Microlife Instant Digital Electronic Thermometer, Model MT1 9S1 R has the similar intended use and similar technological characteristics as the Microlife Instant Digital Electronic Thermometer, Model MT1BI1. Moreover, bench testing contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Instant Digital Electronic Thermometer, Model MT19S1R is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2007

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K070590
Trade/Device Name: Microlife Instant Digital Electronic Thermometer, Model MT19S1R
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 6, 2007
Received: September 7, 2007

Dear Ms. Goldstein-Falk:

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 (240) 276-3150 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

EXHIBIT B

Indications for Use

510(k) Number *(if* known): K070590

Device Name: Microlife Instant Digital Electronic Thermometer, Model MT19S1R

Indications For Use:

Microlife MT19S1R Instant Digital Electronic Thermometer is used for the intermittent measurement and monitoring of oral human body temperature. The intended use of this thermometer is for ages 18 months and above.

Prescription Use __ **AND/OR** **Over-The-Counter Use** __X_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K070590