APR - 6 2011

K103680

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: Sep 28, 2010

Contact: Vice President of Technical and Service
Mr. Gerhard Frick
e-mail: gerhard.frick@microlife.ch
Tel: +41 79 216 0070

2. **Name of the Device:**

Microlife Digital Underarm Thermometer, Model MT18E1-2

3. **Predicate Device Information:**

Microlife Digital Underarm Thermometer, Model MT18E1, K#032364.

4. **Device Description:**

Unlike regular thermometers, the unique elbow of the Digital Underarm thermometer is designed to find the "hotspot" easily and comfortably every time. With its predictive technology, it would be able to speed up the measurement time. With these characteristics, this thermometer can provide both a very high clinical accuracy and quick measurement time.

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

The thermometer adds a fixed offset to match the actual underarm temperature.

5. Intended Use:

Microlife Digital Underarm Thermometer MT18E1-2 is designed specifically for measuring underarm (axillary) temperatures in children ages infant to 6 years old.

6. Comparison to Predicate Devices:

The Microlife Digital Underarm Thermometer, Model MT18E1-2 is substantially equivalent to Microlife Digital Underarm Thermometer, Model MT18E1, K#032364, which has the same intended use for human body temperature measurement but focus especially on underarm temperature and uses unique elbow sensor design.

The Microlife Digital Underarm Thermometer MT18E1-2 and the predicate device are identical in the temperature measurements algorithm and fundamental scientific technology, differing mostly by IC Model and measurement time.

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

Compliance to applicable voluntary standards includes ASTM E1112, as well as IEC60601-1 and IEC60601-1-2 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 in accordance with ASTM E1965 using the Microlife Digital Underarm Thermometer, Model MT18E1-2. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Microlife Clinical Test Protocol outline.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

10. Conclusions:

The Microlife Digital Underarm Thermometer, Model MT18E1-2 has the same intended use and technological characteristics as the Microlife Digital Underarm

Thermometer, Model MT18E1. Moreover, bench testing contained in this submission demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Digital Underarm Thermometer, Model MT18E1-2 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 10021

APR - 6 2011

Re: K103680
Trade/Device Name: Microlife Digital Underarm Thermometer, Model MT18E1-2
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: March 15, 2011
Received: March 16, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony Watson, B.S., M.S., M.B.A.
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): K103680

Device Name: Microlife Digital Underarm Thermometer, Model MT18E1-2

Indications For Use:

Microlife Digital Underarm Thermometer MT18E1-2 is designed specifically for measuring underarm (axillary) temperatures in children ages infant to 6 years old.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/6/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103680