MAY 13 2009

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: K091040

1. **Submitter's Identification:**

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: March 2, 2009

2. **Name of the Device:**

Microlife Digital Infrared Ear Thermometer, Model IR1DV1-1

3. **Predicate Device Information:**

Microlife Digital Infrared Ear Thermometer, Model IR1DE1-1, K#034023

4. **Device Description:**

The Microlife Digital Infrared Ear Thermometer, Model IR1DV1-1 is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces.

The Microlife Digital Infrared Ear Thermometer consists mainly of five parts:

a) IR Thermopile Sensor
b) ASIC
c) E2PROM IC
d) LCD and Backlight
e) 2 Keys, 1 Buzzer

5. **Intended Use:**

The Microlife Digital Infrared Ear Thermometer IR1DV1-1 is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

This device is used probe cover free.

6. Comparison to Predicate Devices:

The Microlife Digital Infrared Ear Thermometer, Model IR1DV1-1 is substantially equivalent to Microlife Digital Infrared Ear Thermometer, Model IR1DE1-1, K#034023, which has the same intended use and is similar in design to the predicate device.

The Microlife Digital Infrared Ear Thermometer IR1DV1-1 and the predicate device are identical in the temperature measurements algorithm and fundamental scientific technology, differing mostly in the construct of probe head, offset and blackbody mode.

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

Compliance to applicable voluntary standards includes ASTM E1965, 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 for the Microlife Digital Infrared Ear Thermometer Model IR1DV1-1 to validate the effectiveness of use without a probe cover. .

9. Conclusions:

The Microlife Digital Infrared Ear Thermometer, Model IR1DV1-1 has the same intended use and similar technological characteristics as the Microlife Digital Infrared Ear Thermometer, Model IR1DE1-1. 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 Digital Infrared Ear Thermometer, Model IR1DV1-1 is substantially equivalent to the predicate device IR1DE1-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2009

Ms. Susan D. Goldstein-Falk
Microlife Intellectual Property GmbH
Espenstrasse 139
9443 Widnau
SWITZERLAND

Re: K091040
Trade/Device Name: Microlife Digital Infrared Ear Thermometer, Model IR1DV1-1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 10, 2009
Received: April 13, 2009

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting 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): K091040

Device Name: Microlife Digital Infrared Ear Thermometer, Model IR1DV1-1

Indications For Use:

The Microlife Digital Infrared Ear Thermometer IR1DV1-1 is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

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)

for ABC LCDR. Collins 05/13/09
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091040