DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 1 3 2004

Re: K033817
Trade/Device Name: Digital Infrared Ear Thermometer,
Model IR1DA1-2 and IR1DE1-2
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 8, 2003
Received: December 11, 2003

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of January 8, 2004 regarding the missing digit in the trade name model numbers.

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 (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.

Ms. Goldstein-Falk

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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K033817

Device Name: Digital Infrared Ear Thermometer, Model IR1DA1-2 and IR1DE1-2

Indications For Use:

The device is an digital infrared Ear 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OTC - ✓

Vicki Hibbard, Interim Branch Chief

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

510(k) Number: K033817

JAN - 8 2004

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K033817

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Max Schmidheiny-Strasse 201
9435 Heerbrugg / Switzerland

Date Summary Prepared: December 8, 2003

Contact: Mr. Gerhard Frick

2. Name of the Device:

Microlife Digital Infrared Ear Thermometer, Models IR1DA1-2 and IR1DE1-2

3. Information for the 510(k) Cleared Device (Predicate Device):

Microlife Digital Infrared Ear Thermometer, Model IR1DE1, K#020725

4. Device Description:

The Microlife Digital Infrared Ear Thermometer, Models IR1DA1-2 and IR1DE1-2 are electronic thermometers using an infrared sensor (thermopile) to detect body temperature from the auditory canal. Their 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) E^2 PROM IC

d) LCD and Blacklight

e) Key "2, Buzzer" 1

5. **Intended Use:**

The device 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.

6. **Comparison to the 510(k) Cleared Device (Predicate Device):**

The Microlife Digital Infrared Ear Thermometers, Models IR1DA1-2 and IR1DE1-2 are substantially equivalent to the original Microlife Digital Ear Thermometer, Model IR1DE1.

The new models IR1DA1-2 and IR1DE1-2 have the same intended use and are similar in design to the 510(k) cleared device.

The IR1DA1-2 and IR1DE1-2 subject devices are identical in functionality and performance to the predicate device, Model IR1DE1, with the only difference being the external shape of the devices, and PCB layout of the devices. The modifications to our original 510(k) cleared device, Model IR1DE1, include performance specifications, ergonomics of the user interface, dimensional specifications 12 sets memory recall and Probe Cover Detection function. The working environmental specification 5-40□, temperature measurements algorithm and its software codes of the modified devices remains unchanged.

The fundamental scientific technology of the modified device remains the same as that of the 510(k) cleared device. The Microlife devices (IR1DA1-2 and IR1DE1-2) works with only a 1-second called a "normal" mode.

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

Compliance to applicable voluntary standards includes ASTM E1112, ASTM E1104 and ASTM E-1965-98, as well as IEC 60601-1 and IEC 60601-1-2 requirements.

Guidance documents included the "FDA Guidance On The Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers", "Deciding When to Submit a 510(k) for a Change to An Existing Devices", and, "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".

8. **Discussion of Clinical Tests Performed:**

Controlled human clinical studies were not conducted for the Microlife Digital Infrared Ear Thermometer modified devices, as well as no low power test as clinical studies/low power testing were conducted for the original unmodified device and remain unchanged. Accuracy performance, reliability and EMC testing is only applicable.

9. **Conclusions:**

The Microlife Digital Infrared Ear Thermometer, Models IR1DA1-2 and IR1DE1-2 have the same intended use and technological characteristics as the unmodified model IR1DE1. Moreover, verification and validation tests contained in this submission demonstrate that the modified portions maintained its original safety and effectiveness. These engineering changes do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.