SEP 1 2 2003

K030961

Attachment #2b

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:_____.

1. Submitter's Identification:

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

Date Summary Prepared: March 24, 2003

2. Name of the Device:

Microlife Digital Basal Thermometer

3. Predicate Device Information:

B-D Digital Basal Thermometer, Model 524560 K#94527

4. Device Description:

The Microlife Digital Basal Thermometer, which uses the Basal Temperature method can be used for helping in family planning in healthy adults by understanding their menstrual cycle and ovulation and interpreting basal temperature changes. This Thermometer provides easy, quick and highly accurate readings over the body temperature range. The body temperature is measured by the thermistor (inside the probe tip) and displayed as numbers on the LCD (liquid crystal diplay) through microprocessor of IC.

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.

For a given time period by applying to R-C oscillator circuit, changes of temperature will correspond to changes of pulse number.

5. **Intended Use:**

The Microlife Digital Basal Thermometer is a device intended for measuring, and aiding in the monitoring and tracking of basal body temperature (BBT) as an aid in ovulation prediction to aid in conception (not to be used for contraception).

6. **Comparison to Predicate Devices:**

The Microlife Digital Basal Thermometer, Model MT1921 is substantially equivalent to B-D Digital Basal Thermometer, Model 524560 K#94527 which have the same intended use and are similar in design to the predicate device.

The Microlife Digital Basal Thermometer MT1921 and the predicate device are identical in functionality and performance with the difference being the external shape of the devices, PCB layout of the devices, ergonomics of the user interface, dimensional specifications, probe tip connection to probe wire for temperature measuring and housing material used.

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 using the Microlife Digital Basal Thermometer MT1921 for measurement and accuracy.

9. **Conclusions:**

The Microlife Digital Basal Thermometer has the same intended use and similar technological characteristics as the B-D Digital Basal thermometer Model 524560,.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 Basal Thermometer 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 12 2003

Microlife Intellectual Property
Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd.
GREAT NECK NY 11021

Re: K030961
Trade/Device Name: Microlife Digital Basal Thermometer Model MT 1921
Regulation Number: None
Regulatory Class: I
Product Code: 85 LHD
Dated: July 24, 2003
Received: July 25, 2003

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); 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment #2a

510(k) Number (if known): K030961

Device Name Microlife Digital Basal Thermometer MT 1921

Indications For Use:

The Microlife Digital Basal Thermometer is a device intended for measuring, and aiding in the monitoring and tracking of basal body temperature (BBT) as an aid in ovulation prediction to aid in conception (not to be used for contraception).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Over-The-Counter Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030961