



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (nikita.steward)

FOLDER: K033820 - 186 pages

COMPANY: MICROLIFE INTELLECTUAL PROPERTY GMBH (MICRINTEPROP)

PRODUCT: THERMOMETER, ELECTRONIC, CLINICAL (FLL)

SUMMARY: Product: MICROLIFE DIGITAL INFRARED FOREHEAD
THERMOMETER, MODEL FR1DM1

DATE REQUESTED: Sep 22, 2015

DATE PRINTED: Sep 22, 2015

Note: Printed



FEB 23 2004

Exhibit #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 510(k) number is: K033820

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 Forehead Thermometer, Model FR1DM1

3. **Predicate Device Information:**

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

4. **Device Description:**

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is an electronic thermometer using an infrared sensor (thermopile) to measure forehead temperature, then get a reading and display it on the LCD.

Its operation is based on measuring the natural thermal radiation emanating from the forehead and the adjacent surfaces.

The Microlife Digital Infrared Forehead Thermometer, consists mainly of five parts:

- a) IR Thermopile Sensor
- b) ASIC
- c) E²PROM IC

- d) LCD and Backlight
- e) Key*2, Buzzer*1

5. **Intended Use:**

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

6. **Comparison to Predicate Devices:**

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is substantially equivalent to the original Microlife Digital Ear Thermometer, Model IR1DE1 in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc.,

The major difference between the Microlife Infrared Forehead Thermometer and the predicate device is the measuring site. The predicate device is measuring ear temperature while the subject device is measuring forehead temperature.

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

Compliance to applicable voluntary standards includes ASTM E1965-98, 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 Infrared forehead thermometer FR1DM1. Clinical data was presented evaluating clinical bias, clinical uncertainty and clinical repeatability per Microlife clinical test protocol for infrared forehead thermometer.

9. **Conclusions:**

The Microlife Infrared Forehead Thermometer, Model FR1DM1, has the same intended use and similar technological characteristics as the Microlife Infrared Ear thermometer Model IR1DE1. Moreover, bench testing contained in this

submission supplied demonstrate that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Infrared Forehead Thermometer, Model FR1DM1, is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2004

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: K033820

Trade/Device Name: Microlife Digital Infrared Forehead Thermometer, Model
FR1DM1
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 8, 2003
Received: December 9, 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 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.

Page 2 – Ms. 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 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 (301) 594-4618. 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 (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

Page 1 of 1

510(k) Number (if known): K033820

Device Name: **Microlife Digital Infrared Forehead Thermometer, Model FR1DM1**

Indications For Use:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

(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: K033820

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter Use
(Optional Format 1-2-96)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2004

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: K033820

Trade/Device Name: Microlife Digital Infrared Forehead Thermometer, Model
FR1DM1

Regulation Number: 880.2910

Regulation Name: Clinical Electronic Thermometer

Regulatory Class: II

Product Code: FLL

Dated: December 8, 2003

Received: December 9, 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 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.

Page 2 – Ms. Falk

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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 (301) 594-4618. 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 (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

2

Exhibit B

Page 1 of 1

510(k) Number (if known): K033820

Device Name: **Microlife Digital Infrared Forehead Thermometer, Model FR1DM1**

Indications For Use:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

(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: K033820

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter Use
(Optional Format 1-2-96)

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 12, 2003

MICROLIFE INTELLECTUAL PROPERTY GMB 510(k) Number: K033820
C/O MDI CONSULTANTS, INC. Received: 11-DEC-2003
55 NORTHERN BLVD., SUITE 200 Product: MICROLIFE DIGITAL
GREAT NECK, NY 11021 INFRARED FOREHEAD
ATTN: SUSAN D. GOLDSTEIN-FALK THERMOMETER, MODEL
FR1DM1

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 09, 2003

MICROLIFE INTELLECTUAL PROPERTY GMB 510(k) Number: K033820
C/O MDI CONSULTANTS, INC. Received: 09-DEC-2003
55 NORTHERN BLVD., SUITE 200 Product: MICROLIFE DIGITAL
GREAT NECK, NY 11021 User Fee ID Number: 122110REHEAD
ATTN: SUSAN D. GOLDSTEIN-FALK THERMOMETER, MODEL
FR1DM1

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier (e.g., Fed Ex, UPS, etc.)
-----	-----
Food and Drug Administration	U.S. Bank
P.O. Box 956733	956733
St. Louis, MO 63195-6733.	1005 Convention Plaza
	St. Louis, MO 63101
	(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

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Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

K033820

Form Approved OMB No. 0910-0511 Expiration Date: August 31, 2006 See instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4)
	Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.html#3a>. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code) MICROLIFE INTELLECTUAL PROPERTY, GHBH MAX SCHMIDHEINY-STRASSE 201 9435 HEERBRUGG HEERBRUGG, 9435 SWITZERLAND	2. CONTACT NAME SUSAN GOLDSTEIN-FALK
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.1 E-MAIL ADDRESS sgoldstein@mdiconsultants.com
	2.2 TELEPHONE NUMBER (Include Area Code) 480 451 7502
	2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 480 614 3169

2003 DEC -9 A 11 21
FDA/CDRH/...

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/oc/mdufma>)

<p>Select an application type:</p> <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	<p>3.1 Select one of the types below:</p> <input checked="" type="checkbox"/> Original Application <p>Supplement Types:</p> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b) (4)

HO
JK
5/12/09
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microlife[®]

K033820

**Microlife Intellectual Property
Max Schmidheiny-Strasse 201
9435 Heerbrugg
Switzerland**

Tel: +41717277000 Fax: +41717277059

RETURN RECEIPT REQUESTED

December 8, 2003

Office of Device Evaluation
U. S. Food & Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA/CDRH/OCE/DID
2003 DEC -9 A 11:22

Dear Sir/Madam:

Enclosed please find an original and a copy of the 510(k) notification for the device that Microlife Intellectual Property intends to market. The device is an Infrared Forehead Thermometer.

We would appreciate a rapid review in that we plan to distribute the product upon your approval.

If there are any questions, please contact me at (480) 451-7502 or (516) 482-9001.
Any correspondence referring to this 510(k) submission should be forwarded to Ms. Susan D. Goldstein-Falk, Microlife Intellectual Property, GmbH, c/o mdi Consultants, Inc., 55 Northern Blvd., Suite 200, Great Neck, NY 11021.

Sincerely,

Microlife Intellectual Property, GmbH

Susan D. Goldstein-Falk
Susan D. Goldstein-Falk
Official Correspondent for
Microlife Intellectual Property, GmbH

SDGF/lo
Enclosure

HO
IF
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Microlife Intellectual Property
Max Schmidheiny-Strasse 201
9435 Heerbrugg
Switzerland
Tel: +41717277000 Fax: +41717277059

RETURN RECEIPT REQUESTED

December 8, 2003

Office of Device Evaluation
U. S. Food & Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, pre-market notification is hereby made of the intention of Microlife Intellectual Property to introduce into interstate commerce for commercial distribution an Infrared Forehead Thermometer to be known as the Microlife Digital Infrared Forehead Thermometer, Model FR1DM1.

The following information is being submitted in conformance with 21 CFR Part 807.87, "FDA Guidance for Format and Content for Premarket Notification (510(k)) Submissions", and, the "FDA Guidance on the Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers", as follows:

SECTION 1 - General Information

a. Applicant: Microlife Intellectual Property, GmbH
Max Schmidheiny-Strasse 201
9435 Heerbrugg
Switzerland
Tel: +41717277000 Fax: +41717277059

Registration No.: Applied For: Awaiting Number

b. Contact Persons: Ms. Susan D. Goldstein-Falk
Official Correspondent for
Microlife Intellectual Property
mdi Consultants, Inc.

microlife[®]

55 Northern Blvd., Suite 200
Great Neck, New York 11021
TEL: (480) 451-7502 (Arizona)
TEL: (516) 482-9001 (New York)
FAX: (516) 482-0186
EMAIL: sgoldstein@mdiconsultants.com

c. Trade/Proprietary Name Including Model Number of Device:

Microlife Digital Infrared Forehead Thermometer, Model FR1DM1

d. Common Name or Classification Name (21 CFR Part 807.87) of Device:

Electronic Thermometer

e. Address of Manufacturing Facility/Sterilization Sites:

This is a non-sterile product.

Foreign Manufacturer:



f. Class in which Device has been placed:

Class II

g. Reason for Premarket Notification:

New Device/ Introduction of a device that is substantially equivalent to a legally marketed device.

h. Notification of Legally Marketed Device Which We Claim Substantial Equivalence (Predicate Device):

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



i. Compliance with Requirements of the Federal FD&C Act:

The General and Restorative Devices Panel (DGRD) has classified this device as Class II, 21 CFR Part 880.2910, Clinical Electronic Thermometer, Product Code 80FLL.

No performance standards or special controls have been developed under Section 514 of the FD&C Act for Clinical Electronic Thermometers. Therefore, no performance standards or special controls apply.

SECTION 2 - Summary & Certification

a. 510(k) Summary or Certification:

Please refer to Exhibit #1, "510(k) Summary", which is our summary of safety and effectiveness information upon which an equivalence determination can be based which can be released to the public.

b. Class III Certification and Summary:

We are not claiming substantial equivalence to a Class III device, and a Class III Certification and Summary is not included for the Microlife Infrared Forehead Thermometer, Model FR1DM1.

c. Kit Certification and Information:

This device is not a kit.

d. Truthful and Accurate Statement

Attached as Exhibit A is our Truthful and Accurate Statement which has been signed by a responsible person of our company.

SECTION 3 - Indications For Use

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1, is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

Please refer to our "Indications for Use" statement which is attached as Exhibit B.

SECTION 4 - Device Description

a. Executive Summary:

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The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1, is substantially equivalent to the original Microlife Digital Ear Thermometer, Model

IR1DE1 in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc.,

The main change between the two devices is the change in the measurement site (forehead instead of ear), which resulted in change of the soft tip, eliminating the need for probe cover, change in the software look up table to fit forehead temperature measurement, and change in the device name.

b. Device Description:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is an electronic thermometer using an infrared sensor (thermopile) to measure forehead temperature, then get a reading and display it on the LCD.

Its operation is based on measuring the natural thermal radiation emanating from the forehead and the adjacent surfaces.

The Microlife Digital Infrared Forehead Thermometer, consists mainly of five parts:

- a) IR Thermopile Sensor
- b) ASIC
- c) E²PROM IC
- d) LCD and Blacklight
- e) Key*2, Buzzer*1

For a complete product description, please refer to the labeling section, "Draft Instruction Manual", EXHIBIT #4.

Technical Specifications of the Model FR1DM1 are outlined below:

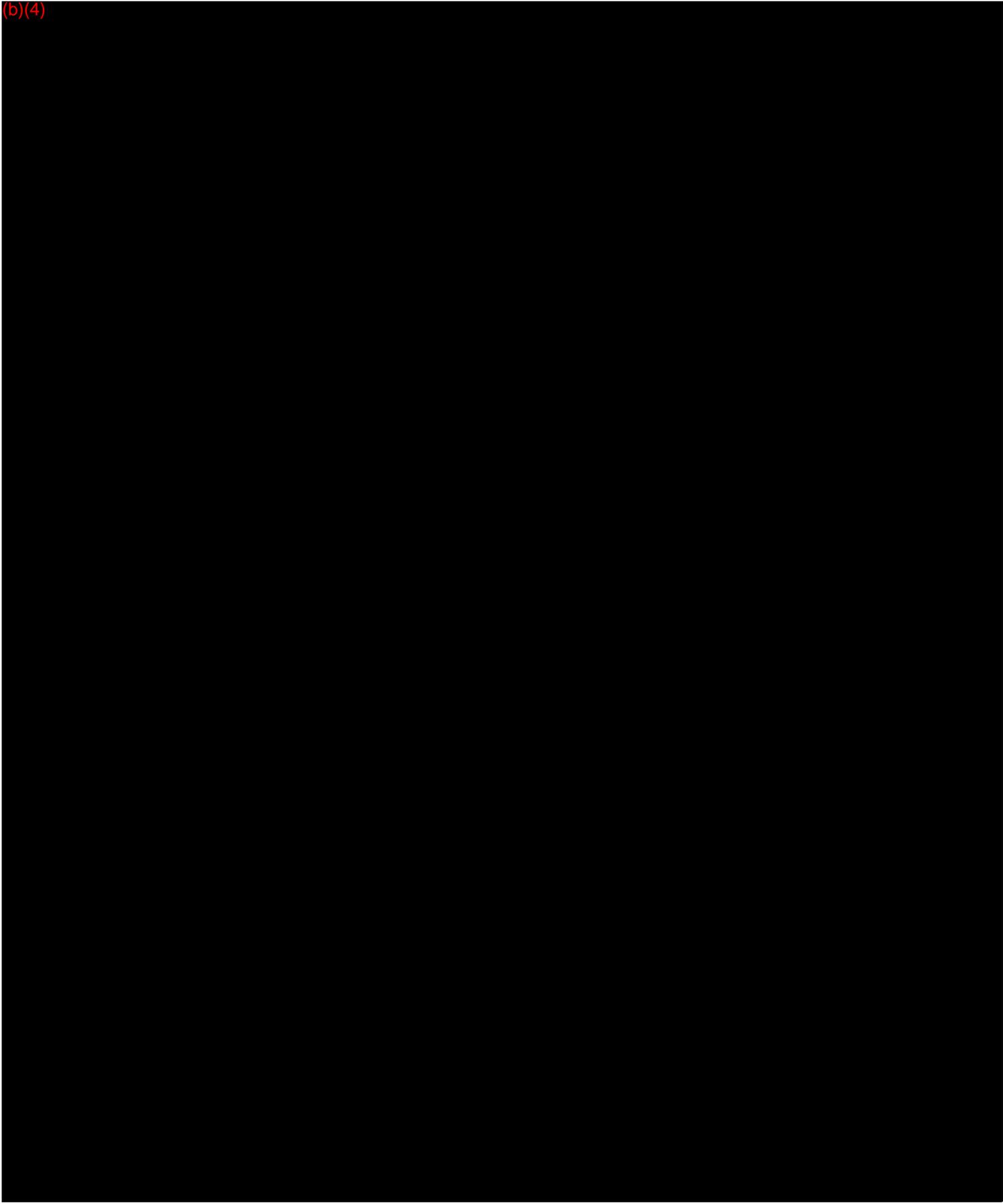
Specification

(b)(4)

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(b)(4)



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18. Weight

49g (including the battery)

The following questions outlined in the DCRND 510(k) Guidance Format are answered as follows:

1. **Is the device life supporting or life sustaining?**

No

2. **Is the device an implant?**

No

3. **Is the device sterile?**

No

4. **Is the device single use or reusable?**

Reusable

5. **Is the device for prescription use?**

No

6. **Is the device for hospital, home, or mobile use?**

Home Use

7. **Does the device contain a drug or biological product as a component?**

No

8. **Is the device a kit?**

No

9. **Is the device software-driven?**

Yes

10. **Is the device electrically operated?**

Battery-powered



11. Are there applicable voluntary standards for this device?

Yes

SECTION 5 - Comparative Information

a. Table of Comparison to Legally Marketed Devices:

The Microlife Infrared Forehead Thermometer, Model FR1DM1 is substantially equivalent to the Microlife Infrared Thermometer, Model IR1DE1, K#020725, Microlife Corporation.

Attached as Exhibit #2 is a "Comparison Chart" outlining differences and similarities between the two (2) devices.

b. Discussion of Similarities and Differences:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is substantially equivalent to the original Microlife Digital Ear Thermometer, Model IR1DE1.

The new model FR1DM1 has the same intended use for human body temperature measurement but focuses on the forehead temperature, not ear temperature, as the 510(K) cleared device, and, is similar in design to the 510(K) cleared device.

The major difference between the Microlife Infrared Forehead Thermometer and the predicate device is the measuring site. The predicate device is measuring ear temperature, while the new model is measuring forehead temperature.

For more details, please refer to Exhibit #1, "510(K) Summary".

c. Comparative Performance Evaluations:

Performance evaluations between both the devices were not conducted, as there are no significant technological characteristic differences between the devices.

d. Clinical Performance Evaluations and Data:

Controlled human clinical studies were conducted using the Microlife Infrared Forehead Thermometer FR1DM1 test protocol. Clinical data is presented evaluating clinical bias, clinical uncertainty and clinical



repeatability per Microlife the clinical test protocol for the Infrared Forehead Thermometer.

Attached as EXHIBIT #13 is our "Infrared Forehead Thermometer Clinical Test Report", which outlines human clinical studies that we conducted for clinical accuracy.

SECTION 6 - Proposed Labeling

Attached as Exhibit #3 is our "Photograph of the Device".

Attached as Exhibit #4 is our "Draft Instruction Manual – FR1DM1".

Attached as Exhibit #14 is our "Label and Marking on the Device".

SECTION 7 - Testing Requirements

Testing information demonstrating safety and effectiveness of the Microlife Infrared Forehead Thermometer, in the intended environment of use, is supported as follows:

The Microlife Infrared Forehead Thermometer conforms to ASTM E-1965, "Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature" in terms of physical requirements and operating parameters.

The following exhibits support our design specification compliance as well as electrical, mechanical and environmental requirements:

- a. Exhibit #5: EMC Test report – FR1DM1
- b. Exhibit #6: IEC60601-1 Safety Test Report
- c. Exhibit #11: Assembly Drawing
- d. Exhibit #12a: Risk Analysis

The following exhibits support our Reliability/ Performance Testing:

- e. Exhibit #8: Reliability Test Protocol and Testing Results

SECTION 8 – Biocompatibility Assessment

Patient-contacting materials is defined as the materials that the user is in direct contact with: for this subject device, the user is in contact with the probe. The materials are (b)(4). Please refer Exhibit #3, "Photograph of



the Device”, which is an illustration of the device, along with corresponding materials. ISO 10993 Biocompatibility Testing was performed on the (b)(4) material which included cytotoxicity, irritation and sensitization testing. Please refer to Exhibit #19a, “Biocompatibility Test Report Results”. Please note that the testing report cites “Microlife Mod. V965”, which is a digital electronic thermometer that uses the identical (b)(4) materials as our Microlife Forehead Thermometer, Model FR1DM1, the subject device for this submission.

Attached as Exhibit #19b is our “Declaration of Identical Materials”, stating that the subject device materials are identical to the materials used in the V965 device.

SECTION 9 – Software Information

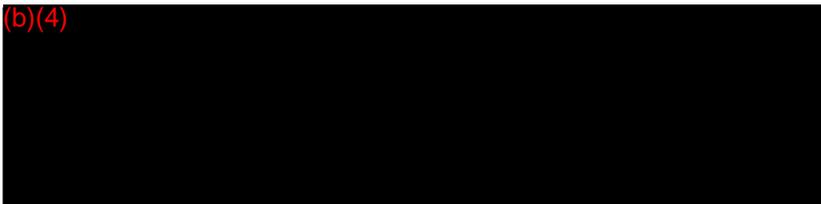
A written description of the Microlife Infrared Forehead Thermometer, Model FR1DM1 software requirements as well as the device performance requirements, including a statement of potential system hazards and software and/or hardware functions implemented as a result of such potential hazards is attached as Exhibit #16, “Software Function Test Report/Software Validation Report for Infra-Red Ear Thermometer”.

Verification and validation activities, to include how the software verification and validation was performed, how the implementation of the system safeguards was assured and which verification and validation activities were performed prior to and after software/ hardware integration is also attached as Exhibit #16.

SECTION 10 – Technical Specifications/Materials and Component Specifications and Drawing

The following exhibits support our technical specifications:

(b)(4)

A large black rectangular redaction box covering the content of the exhibit list.

SECTION 11 – Sterilization Information

This device is marketed as non-sterile, therefore no claims of sterility are made. No expiration date is assigned this device and this product is not supplied sterile.

Certain components of this device are to be cleaned and maintained according to outlined instructions in the operating manual. No reprocessing is claimed.

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The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1, is not intended to connect to any other equipment

Section 12- Standards and Guidance Documents

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".

Additional information: Quality Assurance and Manufacturing Controls:

Microlife Intellectual Property operates in compliance with FDA's Good Manufacturing Practice Regulations for Medical Devices (QSR) (21 CFR Part 820), and, a formally established and controlled Quality Systems Program. Devices are manufactured and assembled to established and controlled device master record requirements by formally trained and supervised personnel.

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA. Our intent to market this device is not considered public information and we have taken precautions to protect this confidentiality.

We would appreciate your reviewing this information at your earliest convenience so that a prompt reply to our request for 510(k) clearance can be processed.

If you have any questions, or require additional information, please call me at (516) 482-9001 or fax me at (516) 482-9001.

Sincerely,

Microlife Intellectual Property, GmbH

A handwritten signature in black ink that reads "Susan D. Goldstein-Falk".

Susan D. Goldstein-Falk
Official Correspondent for
Microlife Intellectual Property, GmbH

SDGF/lo

Attachments (See List Attached)

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LIST OF EXHIBITS

EXHIBIT A	Truthful and Accurate Statement
EXHIBIT B	Indications for Use Statement
EXHIBIT #1	510(k) Summary
EXHIBIT #2	Substantial Equivalence Comparison Chart
EXHIBIT #3	Photograph of the device
EXHIBIT #4	Draft Instruction Manual – FR1DM1
EXHIBIT #5	EMC Test Report – FR1DM1
EXHIBIT #6	IEC 60601-1 Safety Test Report
EXHIBIT #7	Functional Chart
EXHIBIT #8	Reliability Test Protocol and Testing Results
EXHIBIT #9	Electric Circuit
EXHIBIT #10	PCB Drawings
EXHIBIT #11	Assembly Drawing
EXHIBIT #12a	Risk Analysis to component
EXHIBIT #12b	Risk Analysis to user
EXHIBIT #13	Clinical Data and Analysis
EXHIBIT #14	Label and Marking on the Device
EXHIBIT #15	General Functions Test
EXHIBIT #16	Software Test Protocol and Test Results
EXHIBIT #17	Technical Manual

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- EXHIBIT #18** Bill of Materials
- EXHIBIT #19a** Biocompatibility Test Report Results (b)(4)
- EXHIBIT #19b** Declaration of Identical Materials

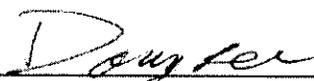
43

EXHIBIT A

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT*
(As Required By 21 CFR 807.87(j))

I certify that, in my capacity as *R & D Vice General Manager* of
Microlife Corporation, I believe to the best of my knowledge, that
all data and information submitted in the premarket notification are truthful and
accurate and that no material fact has been omitted.

(Signature)



(Typed Name)

Donny Lee
(Dated)

2003.09.26
(Premarket Notification (510(k)) Number)

*Must be signed by a responsible person of the firm required to submit the
premarket notification (e.g., not a consultant for the 510(k) submitter).

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Exhibit B

Page 1 of 1

510(k) Number (if known): _____

**Device Name: Microlife Digital Infrared Forehead Thermometer, Model
FR1DM1**

Indications For Use:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)

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Exhibit #1

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
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 Forehead Thermometer, Model FR1DM1

3. Predicate Device Information:

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

4. Device Description:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is an electronic thermometer using an infrared sensor (thermopile) to measure forehead temperature, then get a reading and display it on the LCD.

Its operation is based on measuring the natural thermal radiation emanating from the forehead and the adjacent surfaces.

The Microlife Digital Infrared Forehead Thermometer, consists mainly of five parts:

- a) IR Thermopile Sensor
- b) ASIC
- c) E²PROM IC

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- d) LCD and Blacklight
- e) Key*2, Buzzer*1

5. Intended Use:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

6. Comparison to Predicate Devices:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is substantially equivalent to the original Microlife Digital Ear Thermometer, Model IR1DE1 in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc.,

The major difference between the Microlife Infrared Forehead Thermometer and the predicate device is the measuring site. The predicate device is measuring ear temperature while the subject device is measuring forehead temperature.

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

Compliance to applicable voluntary standards includes ASTM E1965-98, 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 Infrared forehead thermometer FR1DM1. Clinical data was presented evaluating clinical bias, clinical uncertainty and clinical repeatability per Microlife clinical test protocol for infrared forehead thermometer.

9. Conclusions:

The Microlife Infrared Forehead Thermometer, Model FR1DM1, has the same intended use and similar technological characteristics as the Microlife Infrared Ear thermometer Model IR1DE1. Moreover, bench testing contained in this

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submission supplied demonstrate that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Microlife Infrared Forehead Thermometer, Model FR1DM1, is substantially equivalent to the predicate device.

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Comparison to the 510(k) Cleared Device

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is substantially equivalent to the original Microlife Digital Ear Thermometer, Model IR1DE1.

The new model FR1DM1 has the same intended use for human body temperature measurement but focus on the forehead temperature, not ear temperature as the 510(K) cleared device, and is similar in design to the 510(K) cleared device.

Because the environment temperature affects the forehead thermometer very much, so Microlife Intellectual Property Infra red forehead thermometer FR1DM1 uses two infrared sensors to measure forehead temperature and ambient temperature at the same time, then refer to the offset table established by extensive clinical tests that relates the skin temp and ambient to get a reading and display on the LCD, which is much different from the predicate device.

A comparison chart follows:

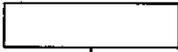
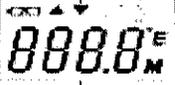
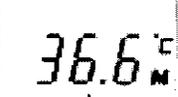
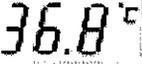
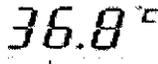
Item	MicroLife IR1DE1	MicroLife FR1DM1	Comparison
Thermometer type	Infrared ear thermometer	Infrared Forehead thermometer	Different
Intended use	Intermittent measurement of human body temperature in the home	Intermittent measurement of human body temperature in the home	Same
Labeling	MicroLife IR1DE1 Thermometer	MicroLife FR1DM1 Thermometer	Different
Components	IR Thermopile sensor	IR Thermopile sensor	Same
	ASIC	ASIC	Same
	E ² PROM IC	E ² PROM IC	Same
	LCD and Backlight	LCD and Backlight	Same
	Key * 2 , Buzzer *1	Key*2 , Buzzer *1	Same
Signal processing and Display	IR sensor → Amplifier → A/D → Microprocessor → LCD	IR sensor → Amplifier → A/D → Microprocessor → LCD	Same
Power requirements	CR2032, 1.5V Battery *1	CR2032, 1.5V Battery *1	Same

Displayed Temperature Range	32 ~ 42.2 °C (89.6 ~ 108 °F)	34 ~ 42.2 °C (93.2 ~ 108 °F)	Different
Operating Ambient Temperature Range	5 ~ 40 °C (41 ~ 104 °F)	16 ~ 40 °C (60.8 ~ 104 °F)	Different
Storage Ambient Temperature Range	-25°C to +55°C (-13 °F to 131°F)	-25.0°C ~ 55.0°C (-13.0°F ~ 131.0°F)	Same
Display Resolution	0.1°C or °F	0.1°C or °F	
Accuracy for display Temperature Range	±0.2°C (32 ~ 42.2°C),	±0.2°C(34 ~ 42.2°C)	Same
Battery Life	1 years / 1000 measurements	1 years/ 1000 measurements	Same
Memory	1 set, last measurement	12 set, last measurement	Different
Response time	Normal mode 1s	Normal mode 1s	Same
Low / Dead Battery Warning	Low Battery : 2.7V Dead Battery : 2.6V	Low Battery : 2.7V Dead Battery : 2.6V	Same
Fever alarm	Yes	Yes	Same
Power Auto off	1 min. , after last operation	1 min., after last operation	Same
Offset	No	Yes	Different
Probe cover	Yes	No	Different
Storage case	Yes	Yes	Different
Read site	Tympanic	Forehead	Different
Display type	LCD	LCD	Same
Back light	Yes	Yes	Same
Sensor type	Thermopile	Thermopile	Same
Measuring mode	Normal mode only	Normal mode only	Different

A comparison to LCD display between IR1DA1 and IR1DE1

IR1DE1 LCD Display

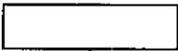
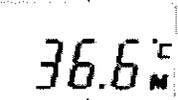
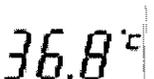
(For ear temperature measurement only)

Operation	LCD Display	Description
Off		* Blank
Press ON/OFF Button		* Power ON: <ul style="list-style-type: none"> • All segments displayed for 2 second • Backlight activated • No beep
Press Button Anytime to Switch OFF		* Memory function: <ul style="list-style-type: none"> • Last reading displayed for 3 seconds • Backlight kept on for 2 seconds
		* Self-test: <ul style="list-style-type: none"> • Displays "Err" if system malfunction • 3 short beeps • Auto shut-off after a 60 second idle
		* Ready for measurement: <ul style="list-style-type: none"> • 1 short beep • °C (or °F) icon flashing. • Press and hold Start for 1 second
		* Completion of a measurement: <ul style="list-style-type: none"> • 1 long beep heard and LED turned on GREEN for 5" if reading less than 37.5°C • 10 short beeps heard and LED turned on RED for 5" if reading equal to or greater than 37.5°C • Backlight turned on at the same time for 5"
		* Further measurement <ul style="list-style-type: none"> • °C (or °F) icon flashing again to indicate readiness for next measurement

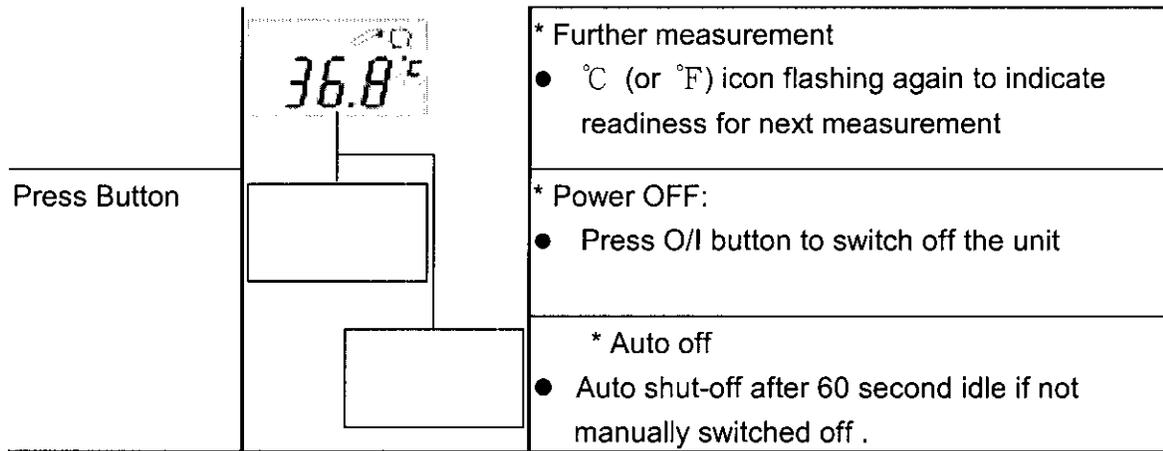
Press Button		* Power OFF: ● Press O/I button to switch off the unit
		* Auto off ● Auto shut-off after 60 second idle if not manually switched off .

FR1DM1 LCD Display

(For forehead temperature measurement only)

Operation	LCD Display	Description
Off		* Blank
Press ON/OFF Button		* Power ON: ● All segments displayed for 2 second ● Backlight activated ● No beep
Press Button Anytime to Switch OFF		* Memory function: ● Last reading displayed for 3 seconds ● Backlight kept on for 2 seconds
		* Self-test: ● Displays "Err" if system malfunction ● 3 short beeps ● Auto shut-off after a 60 second idle
		* Ready for measurement: ● 1 short beep ● °C (or °F) icon flashing. ● Press and hold Start for 1 second
		* Completion of a measurement: ● 1 long beep heard and LED turned on GREEN for 5" if reading less than 37.5°C 10 short beeps heard and LED turned on RED for 5" if reading equal to or greater than 37.5°C ● Backlight turned on at the same time for 5"

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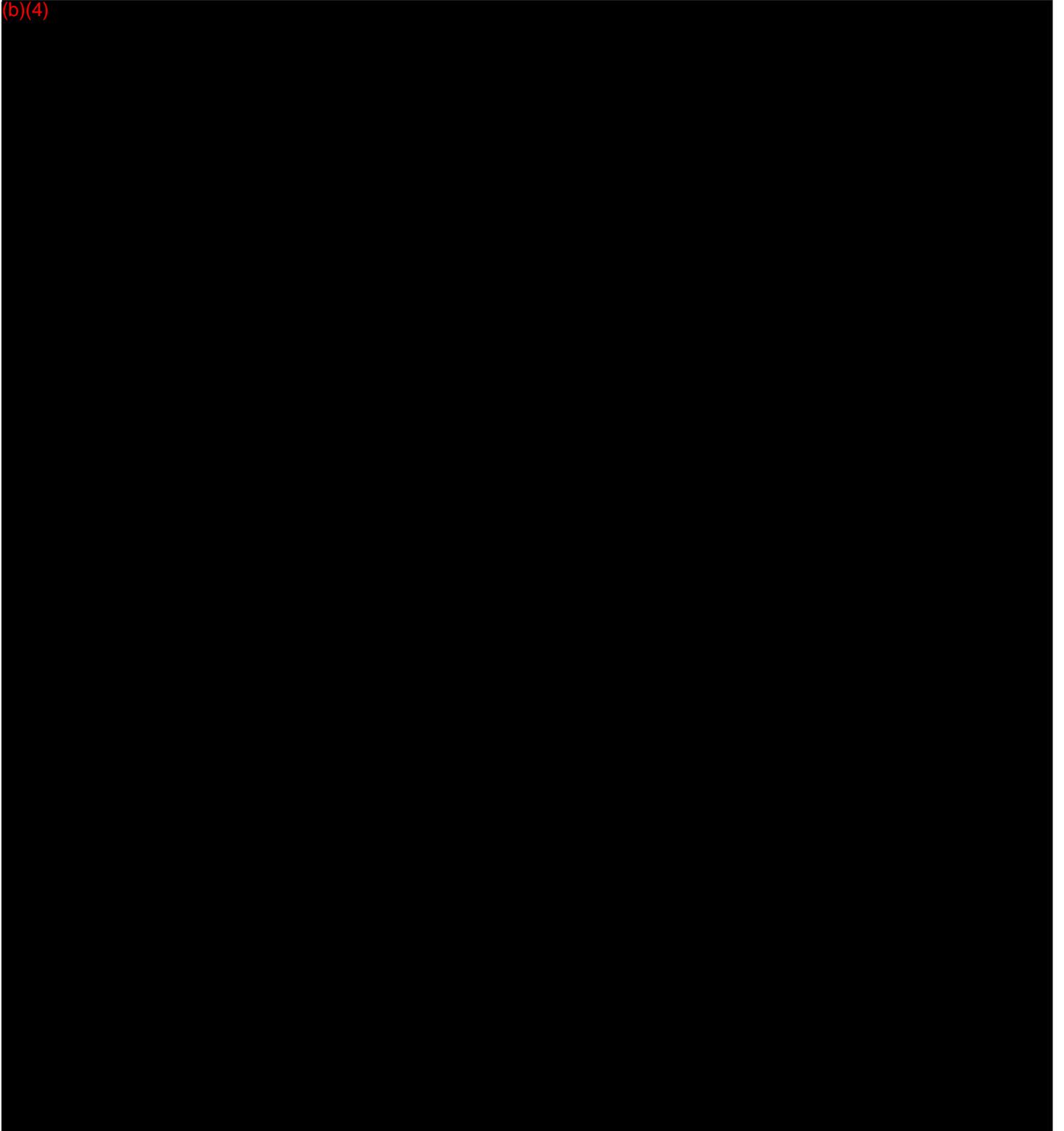


The temperature measurement algorithm and its program codes of the IR1DE1 and FR1DM1 is the same.

EXHIBIT #3

Illustration of FR1DM1 and V965

(b)(4)



Digital Infrared Forehead Thermometer

1 sec. Measurement / Scan-Peak-method

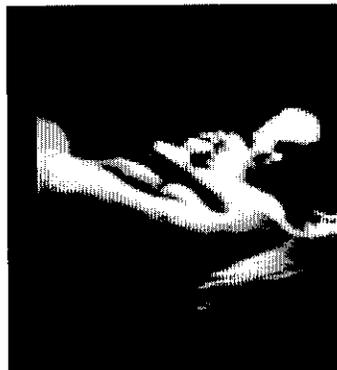
Fever alarm

Illuminated Display / Nite Glow

Memory

Celsius - Fahrenheit switchable

Beeper



microlife FR 1DM1

Digital Infrared Forehead Thermometer



microlife

MicroLife AG
Max Spennberg-Strasse 201
9435 Heidenegg / Switzerland
Tel. +41 / 71 727 70 30
Fax +41 / 71 727 70 39
Email admin@microlife.ch
www.microlife.com

microlife

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**Digital Infrared Forehead Thermometer
Instruction Manual**

We congratulate you on your purchase of the Microcole Digital Infrared Forehead Thermometer. The Microcole Digital Infrared Forehead Thermometer FR1DM1 is a high quality product incorporating the latest technology and tested accuracy with international standards. With its unique technology, the FR1DM1 can provide a stable, heat-interference-free reading with each measurement. The instrument performs a self-test every time it is switched on to always guarantee the specified accuracy of measurements.

The Microcole Digital Infrared Forehead Thermometer FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature in the home. It is intended for use on people of all ages.

Please read these instructions carefully before using the instrument and keep them in a safe place.

Table of Contents

1. The Advantages of your Microcole Digital Infrared Forehead Thermometer
2. Important Safety Instructions
3. Product Description
4. How the Microcole Digital Infrared Forehead Thermometer Measures Body Temperature
5. Control Displays and Symbols
6. Directions for Use
7. Changing from Fahrenheit to Celsius and vice-versa
8. Error Messages
9. How to recall 12 readings in the memory mode
10. Cleaning and Storage
11. Technical Specifications
12. Replacing the Battery
13. Guarantee
14. www.microcole.com

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1. The Advantages of your Microlic Digital Infrared Forehead Thermometer

Measurement in 1 second
The innovative infrared technology allows measurement of forehead temperature in only 1 second!

Accurate and reliable

Due to the unique probe assembly construction, the advanced infrared sensor, and the complete calibration process this unit can offer a very accurate and reliable forehead temperature measurement.

Gentle and Easy to Use

- Appealing Penguin style delights the children
- No need Probe Covers at all, which makes the thermometer simple and easy to use.
- The Microlic Digital Infrared Forehead Thermometer FR1DM1 can be used without interference to daily lifestyle. A measurement can be taken even while a child is sleeping.
- The Microlic Digital Infrared Forehead Thermometer FR1DM1 is less threatening to a child than a rectal thermometer and more pleasant to use than an oral thermometer.

Auto-Display Memory

The product displays the last reading automatically for 2 seconds when the unit is switched ON.

Multiple Reading Recalls

When entering into the memory mode, users will be able to recall the last 12 readings, enabling tracking of temperature variation in a more efficient way.

Safe and Hygienic

- No risk of broken glass or mercury ingestion.
- Completely safe for use on children.

Fever Alarm

10 short beeps alert the patient that he/she may have fever.

2. Important Safety Instructions

- Never use the thermometer for purposes other than those it has been intended for. Please follow the general safety precautions when using on children.
- Never immerse the Microlic Digital Infrared Thermometer FR1DM1 into water or other liquids (not waterproof). For cleaning and disinfecting please follow the instructions in the "Cleaning and Storage" section.

2

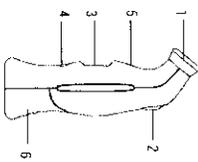
- Keep the instrument away from direct exposure to the sun and keep it in a dust free, dry area at the temperature between 10° - 40° (50°F - 104°F).
- Do not use the thermometer if there are signs of damage on the measuring tip or on the instrument itself. If damaged, do not attempt to repair the instrument! Please contact your nearest Microlic customer service bureau.
- This Microlic Digital Infrared Forehead Thermometer consists of high-quality precision parts. Do not drop the instrument! Protect it from severe impact and shock. Do not twist the instrument and the measuring probe!

WARNING:

- Use of this infrared forehead thermometer is not intended as a substitute for consultation with your physician.
- Thermometer is not waterproof! Please NEVER immerse into liquids!

3. Product Description

- (1) Probe
- (2) Start button
- (3) LCD Display
- (4) ON button
- (5) LED Indicator
- (6) Battery Cover



4. How the Microlic Digital Infrared Forehead Thermometer Measures Forehead Temperature

The Microlic Digital Infrared Forehead Thermometer FR1DM1 measures infrared energy radiated from the artery under the skin of forehead and the surrounding tissue. This energy is collected through the lens and converted to a temperature value. The measured reading obtained directly from the center of forehead can ensure the most accurate ear temperature. Measurements taken from the other surrounding tissue of the forehead generate lower readings and may result in misdiagnosis of a fever.

To avoid an inaccurate measurement:

- Switch on the thermometer by pressing the ON button

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- After one beep is heard (and the temperature scale is on), the LCD will blink the probe tip at the top of forehead. Make sure the opening of probe is contacted closely with the skin.
- Press the Start button for 1 second and keep the probe at the forehead until the thermometer generates a long beep to identify the completion of the measurement.

The Microline Digital Infrared Forehead Thermometer FR1DM1 has been clinically tested and proven to be safe and accurate when used in accordance with its operating instruction manual.

5. Control Displays and Symbols

LCD Display	Display Meaning	Description
	All segments displayed	Press the On/Off button to turn on the unit, all segments will be shown for 2 seconds
	Memory	The last reading will be shown on the display automatically for 3 seconds.
	Ready	The unit is ready for the measurement, the "C" or "F" icon will keep flashing.
	Measurement complete	The reading will be shown on the LCD display with the "C" or "F" icon flashing, the unit is ready again for the next measurement.
	Low battery indication	When the unit is turned on, the battery icon will keep flashing to remind the user to replace the batteries

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6. Directions for Use

1. Press the On/Off button. The LCD is activated to show all segments for 2 seconds.
2. The last measurement reading will be shown on the display automatically for two seconds with the "M" icon.
3. When the "C" or "F" icon is flashing, a beep sound is heard and the thermometer is ready for the measurement.
4. Place the probe at the center of forehead. Make sure the opening of probe is completely contacted with the skin of forehead.
5. Press the "START" button. Release it when you hear a beep sound. This is the reminding signal that confirms the end of measurement.



6. Remove the thermometer from the forehead. The LCD displays the measured temperature.
7. In order to assure the accurate readings, please wait at least 30 seconds after 3-5 continuous measurements.

NOTE:

- Always take the temperature in the same location, since the temperature readings may vary from different locations.
- Please wait for a few minutes to take the ear temperature after sleeping.
- In the following situations it is recommended that three temperatures in the same location at forehead be taken and the highest one taken as the reading.
 - 1) New born infants in the first 100 days.
 - 2) Children under three years of age with a compromised immune system and for whom the presence or absence of fever is critical.
 - 3) When the user is learning how to use the thermometer for the first time until the user has familiarized himself/herself with the instrument and obtains consistent readings.

7. Changing from Fahrenheit to Celsius and vice versa

The Microline Digital Infrared Thermometer FR1DM1 can display temperature measurements in either Fahrenheit or Celsius. To Change

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the temperature scale from Fahrenheit to Celsius or vice versa, press Start when power off for more than 3 seconds until "...", and then flashing "F" (or "C") icon are shown on the LCD. Press and release Start to switch from F to C, or vice versa. If the scale is not switched (Start not pressed and released) for 5 seconds, the LCD will indicate ready-for-measurement (same as normal turn-on).



8. Error Messages

Display / Problem Display Meaning and Remedy

	Measured Temperature too high	Displays "H" when measured temperature higher than 42.2 °C (106.0 °F) or 100.0 °C (212.0 °F)
	Measured Temperature too low	Displays "L" when measured temperature lower than 34.0 °C (93.2 °F) or 0 °C (32.0 °F)
	Ambient temperature too high	Displays "H" in conjunction with the "▲" when ambient temperature is higher than 40.0 °C or 104.0 °F
	Ambient temperature too low	Displays "L" in conjunction with the "▼" when ambient temperature is lower than 15.0 °C or 59.8 °F
	Error function display	When system has malfunction. Please check if the battery has been loaded correctly. Also check polarity (<-> and <->) of batteries.
	Blank display	
	Dead battery indication	If the steady battery icon is the only symbol shown on the display, the batteries should be replaced immediately.

9. How to recall 12 readings in the memory mode

Press the START button to enter Memory Mode when the power is off. The memory icon "M" will flash.

Press and release the START button to recall the latest reading. The LCD will display 1 along with the memory icon when the button is pressed and the most recent reading when the button is released.



Press and release the START button again to recall the second latest reading.



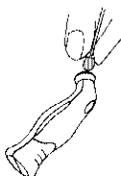
Press and release the START button consecutively to recall readings in succession, up to the last 12 readings.



Pressing and releasing the START button after the last readings have all been recalled will resume the above sequence from reading 1.

10. Cleaning and Storage

Use an alcohol swab or cotton swab moistened with alcohol (70% isopropyl) to clean the thermometer casing and the measuring probe. Ensure that no liquid enters the interior of the thermometer. Never use abrasive cleaning agents, thinners or benzene for cleaning and **never immerse the instrument in water or other cleaning liquids.** Take care not to scratch the surface of the LCD. Remove the battery from the instrument if it is not required for extended periods of time in order to avoid damage to the thermometer resulting from a leaking battery.



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11. Technical Specifications

Type:	Digital Infrared Thermometer FR 1DM1
Measuring Range:	Forehead measuring range: 34.0°C - 42.2°C (93.2°F - 108.0°F) Wide measuring range: 0 °C to 100.0 °C (32.0 °F to 212.0 °F)
Resolution	0.1°C / 0.2°F
Accuracy:	Laboratory: ±0.3 °C, 34.0 - 42.2 °C (±0.5 °F, 93.2 - 108.0 °F) ±1 °C, 0 - 31.9 °C, 42.3 - 100.0 °C (±2 °F, 32.0 - 89.5 °F, 108.1 - 212.0 °F)
Display:	Liquid Crystal Display, 4 digits plus special icons
Acoustic:	a. The unit is turned ON and ready for the measurement: 1 short „beep“ sound b. Complete the measurement: 1 long beep sound c. System error or malfunction: 3 short „beep“ sounds.
Memory:	a. Auto-Display the last measured temperature b. 12 memories recalled in Memory mode.
Note show:	a. The display will be lighted for 4 seconds when the unit is turned ON. b. The display will be lighted again for 5 seconds when the measurement has been completed.
Operating temperature:	16 °C to 40 °C (60.8 °F to 104 °F)
Storage/Transport temperature:	-25 °C to +55 °C (13 °F to 131 °F)
Automatic Switch-off:	Approx. 1 minute after last measurement has been taken.
Battery:	CR2032 BATTERY (X1) - at least 1000 measurements
Dimensions	14 mm (L) x 26 mm (W) x 20 mm (H)
Weight:	45g (with battery) 40g (w/o battery)
Standards:	Complies with IEC60601-1-2 and ASTM E 1965 requirements

According to the Medical Product User Act a biennial technical inspection is recommended for professional users. Please observe the applicable disposal regulations.

12. Replacing the Battery

The Microfite Digital Infrared Thermometer is supplied with one lithium battery, type CR2032. Replace with a new CR2032 battery when the flashing battery symbol appears on the LCD display. Using a screwdriver to loosen the screws from battery cover as shown, remove the battery cover and replace CR2032 battery.



13. Guarantee

Subject to the following conditions this high-quality measuring instrument is covered by a **two year guarantee** from the date of purchase. Warranty claims must be lodged within the guarantee period.

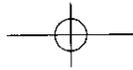
This product was manufactured with the utmost of care according to international quality standards. Should you have reason for complaints despite this, please send the instrument, accompanied by the completed Guarantee Card with dealer's stamp as well as original proof of purchase directly or through your medical supplier to your closest Microfite Distributor. Damage resulting from incorrect use is not covered by the guarantee. Battery and packaging are excluded from the guarantee. Claims beyond this, including claims for damages, are excluded.

Name and address of responsible dealer:

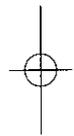
IB FRIDM1 2003.9.20 4:04 AM Page 10

www.microlife.com

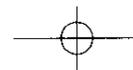
Detailed user information about our thermometers and blood pressure monitors as well as services can be found at www.microlife.com



10



11

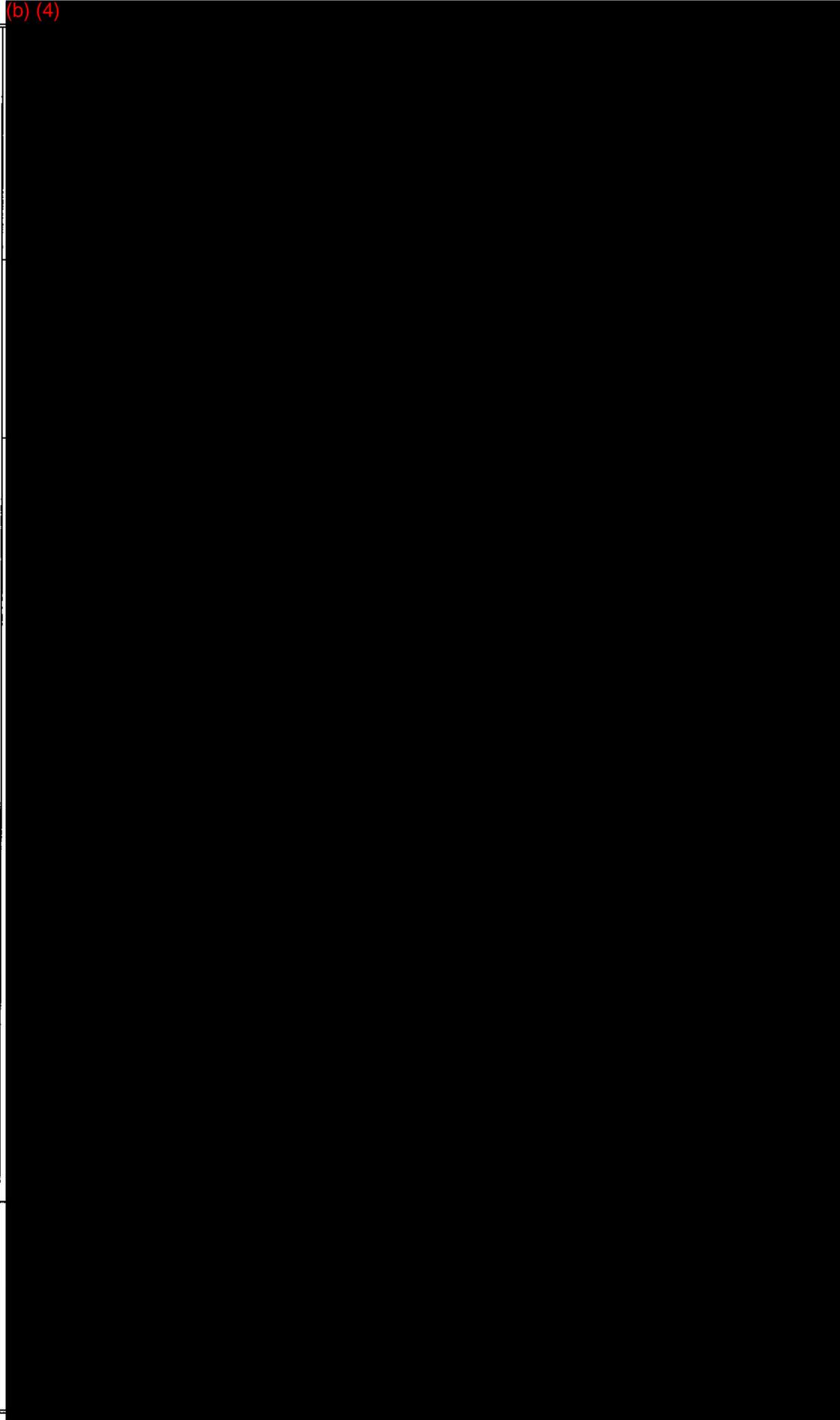


6e1

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EXHIBIT #9

CIRCUIT DIAGRAM



Approved by:	Donny Lee	Checked by:	ZQL	Drawn by:	ZQL
--------------	-----------	-------------	-----	-----------	-----

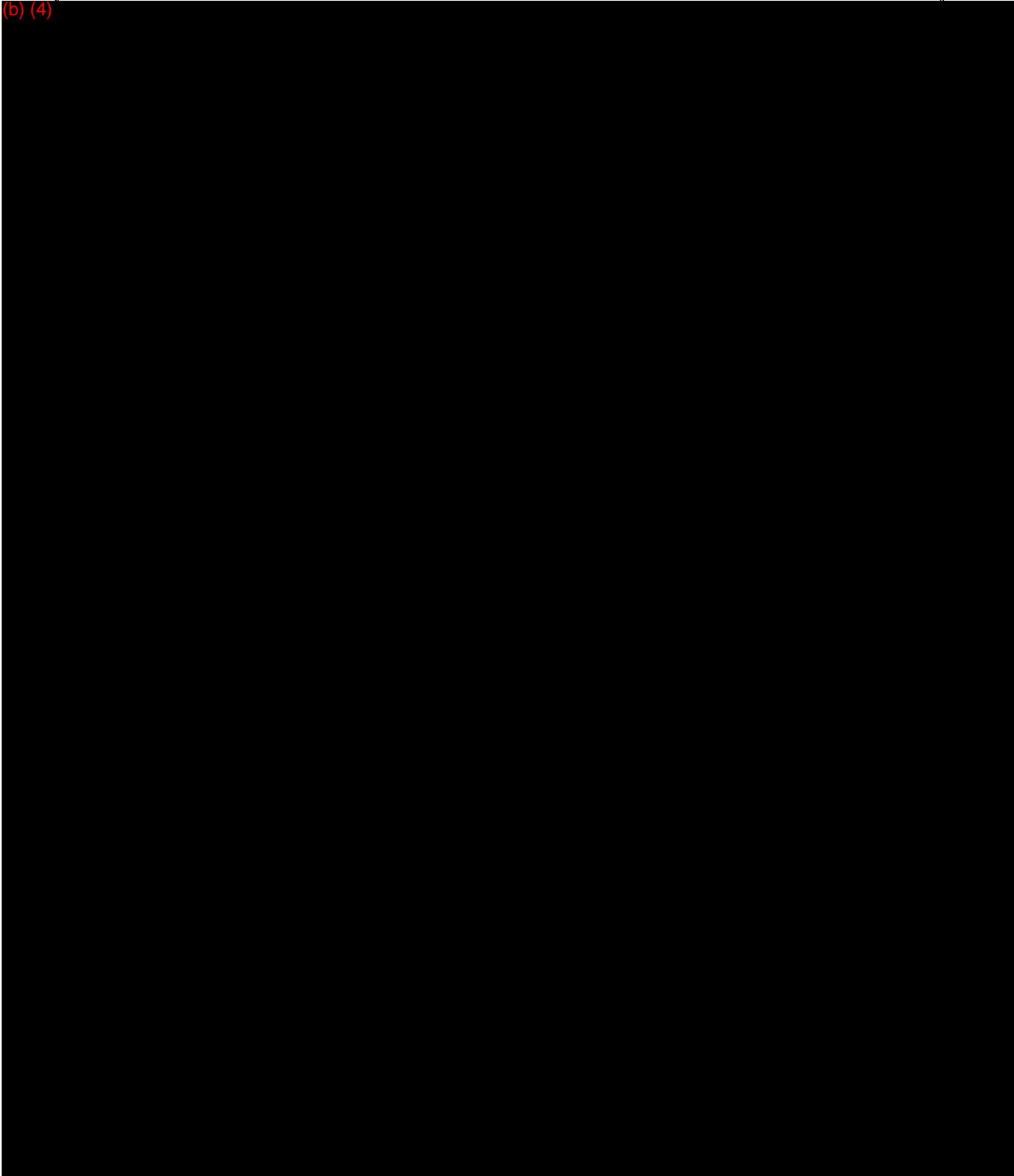
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EXHIBIT #10

PCB LAYOUT

(b) (4)

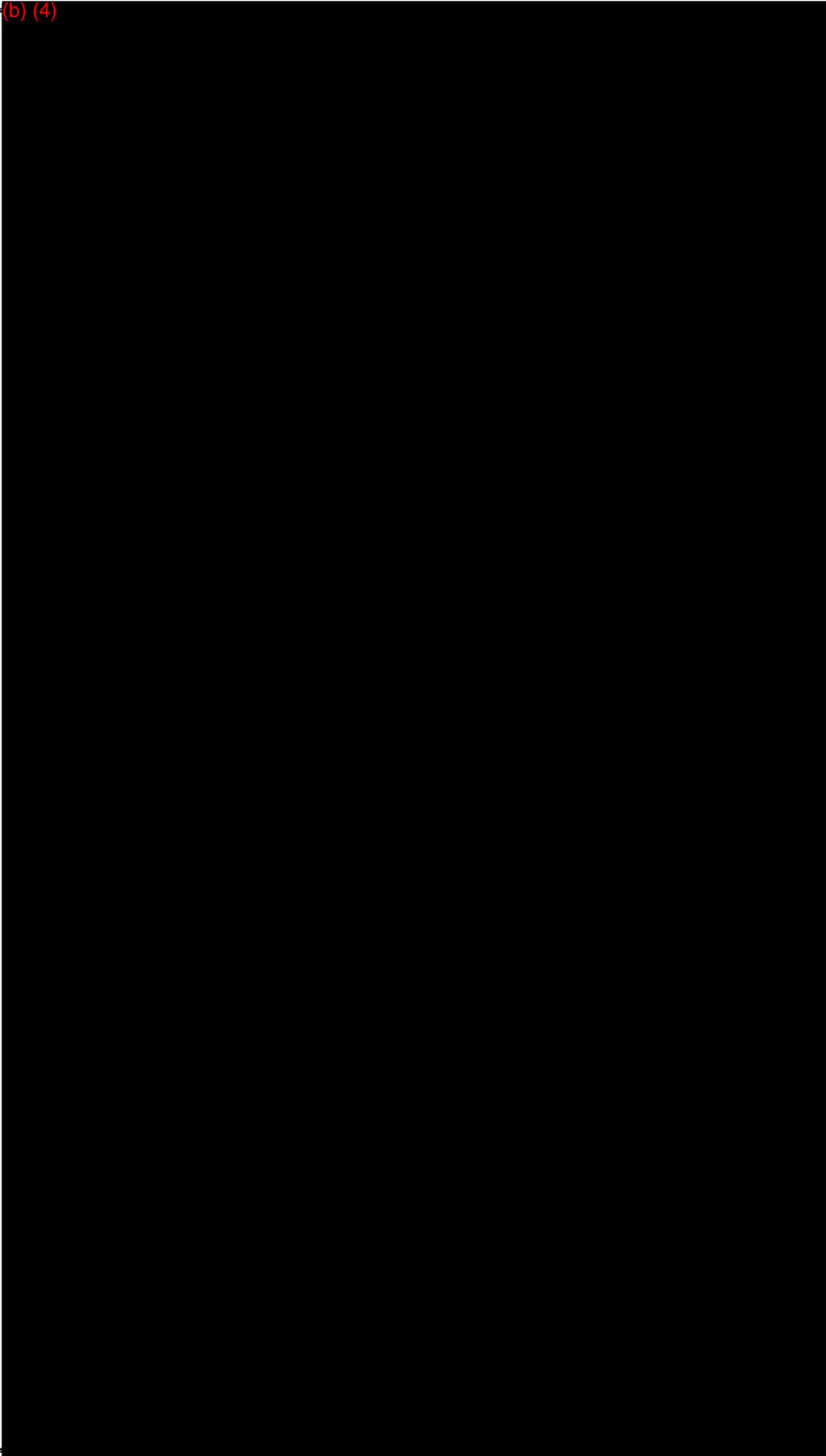


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EXHIBIT #11

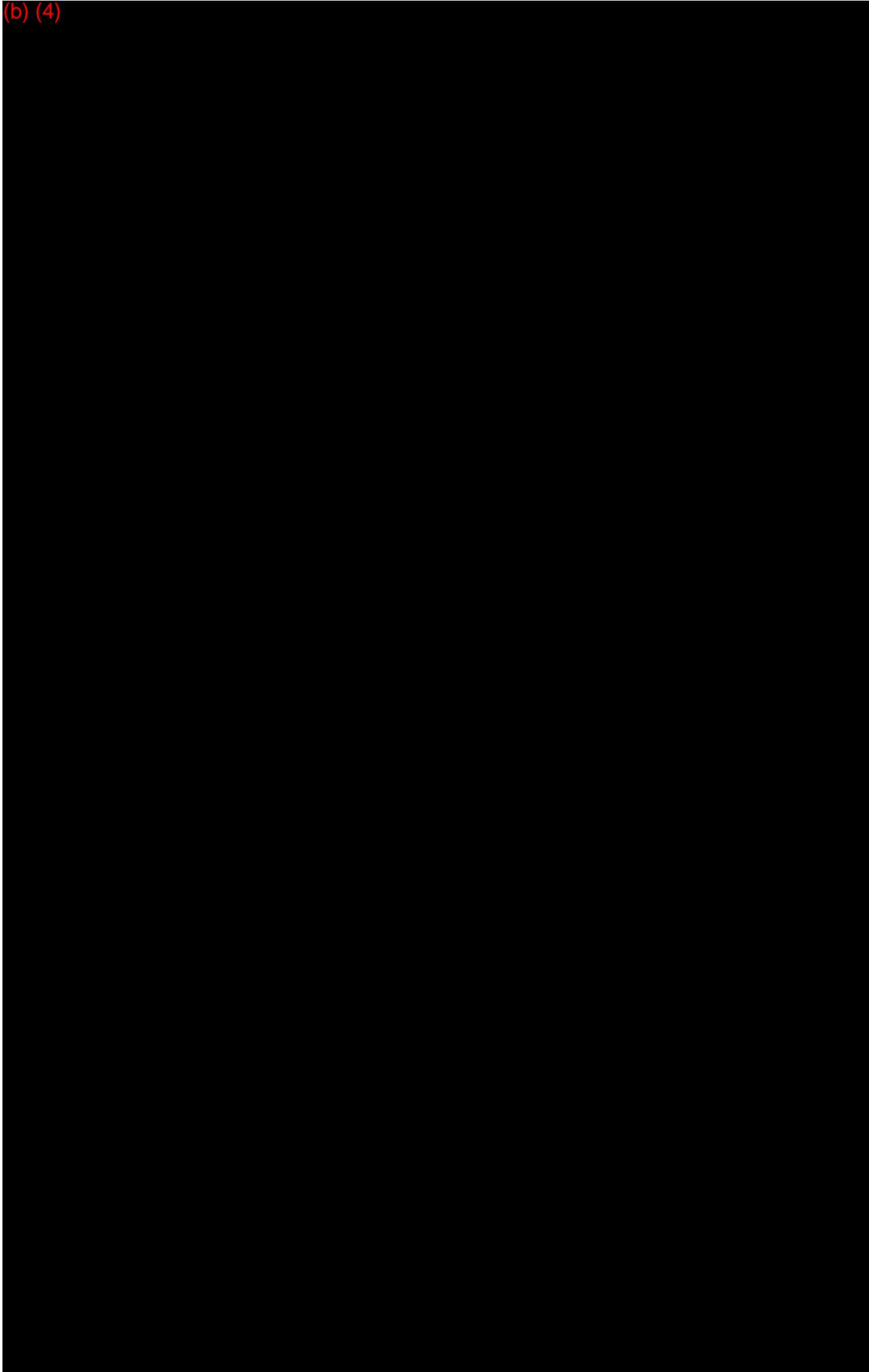
ASSEMBLE DRAWING

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(b) (4)

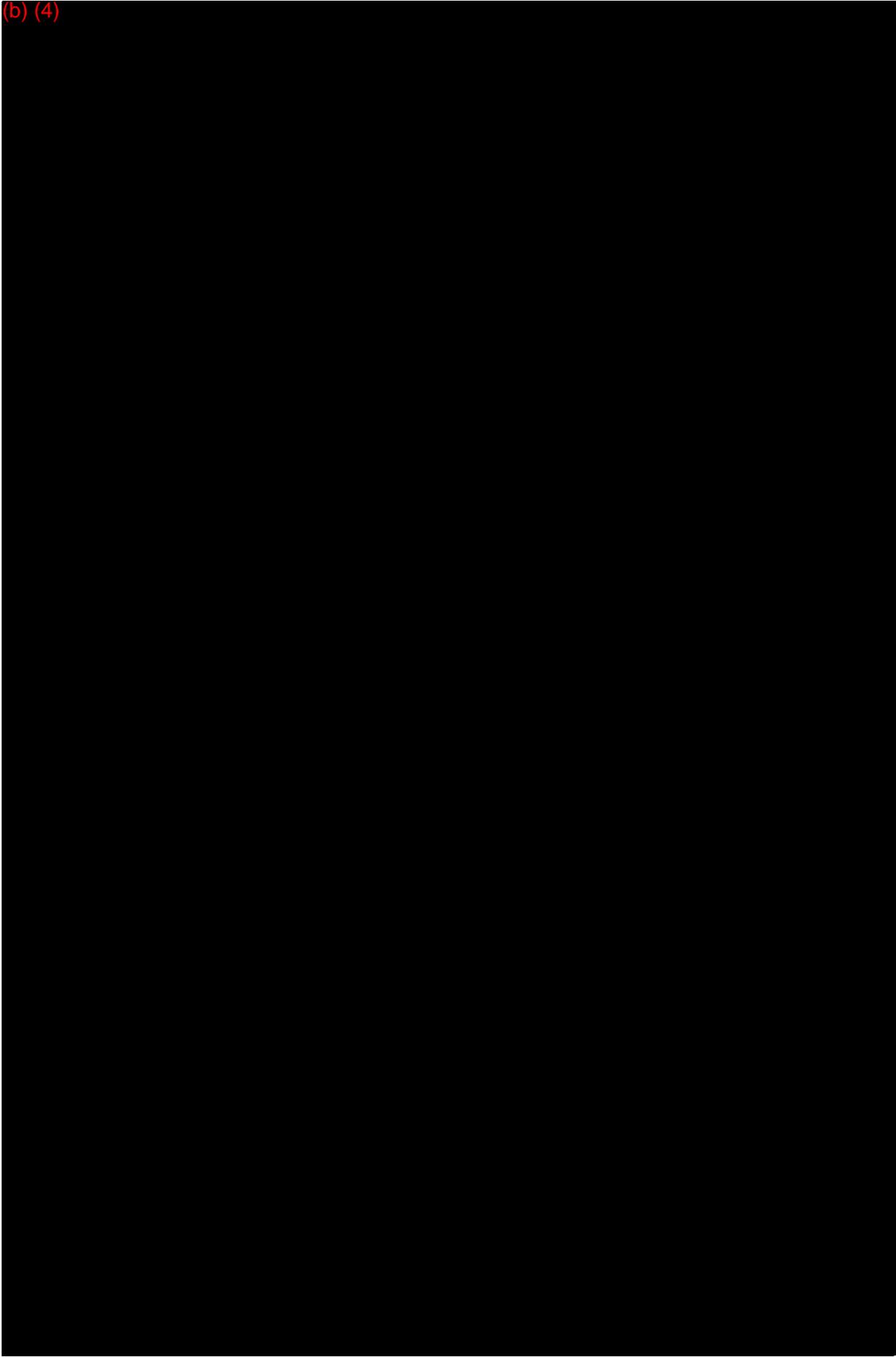
(b) (4)



FRIDM1 FAILURE MODE AND EFFECTS ANALYSIS TO COMPONENT

EXHIBIT #12a

(b) (4)



Page 2 of 4

EXHIBIT #12a

(b) (4)

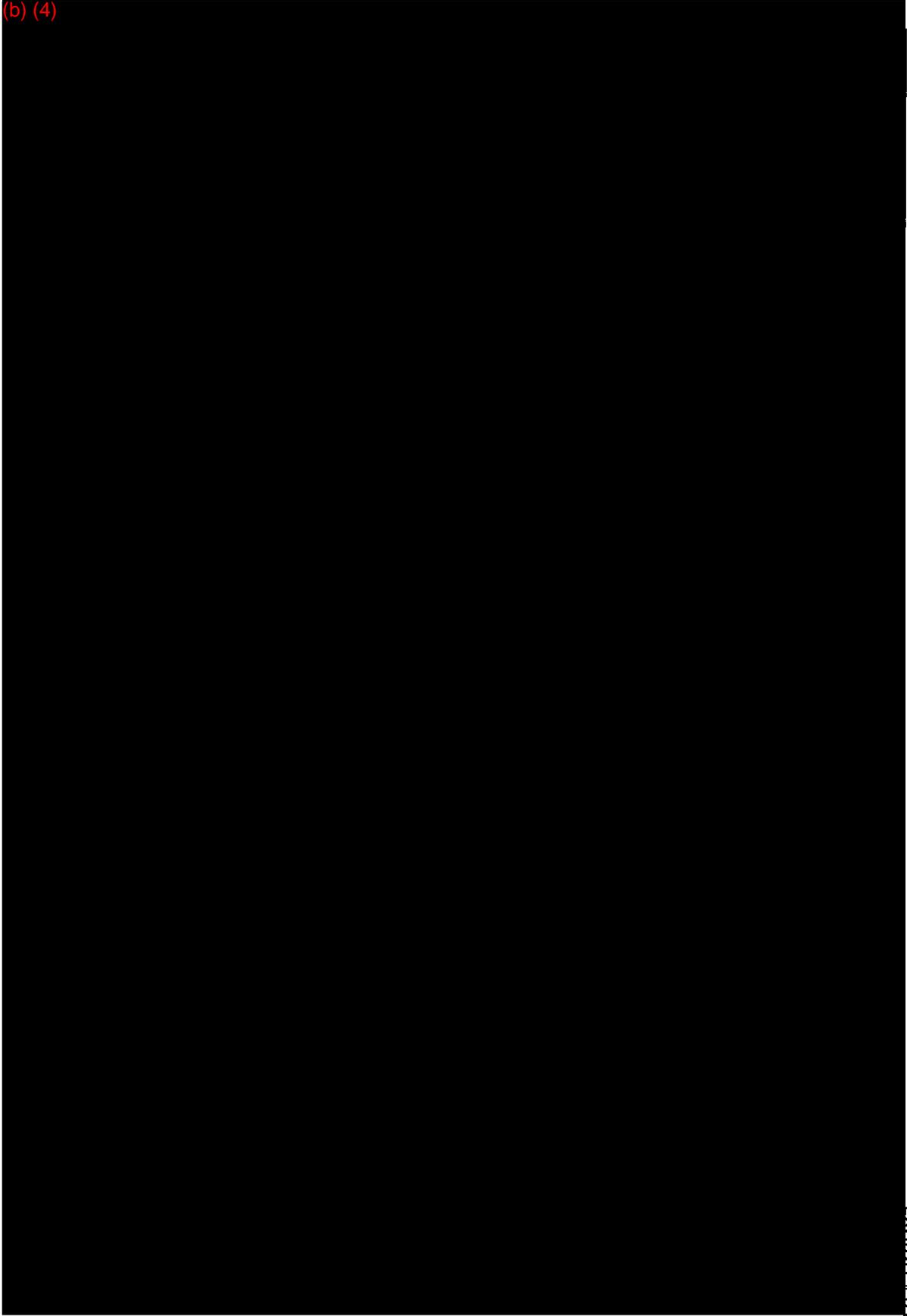


EXHIBIT #12a

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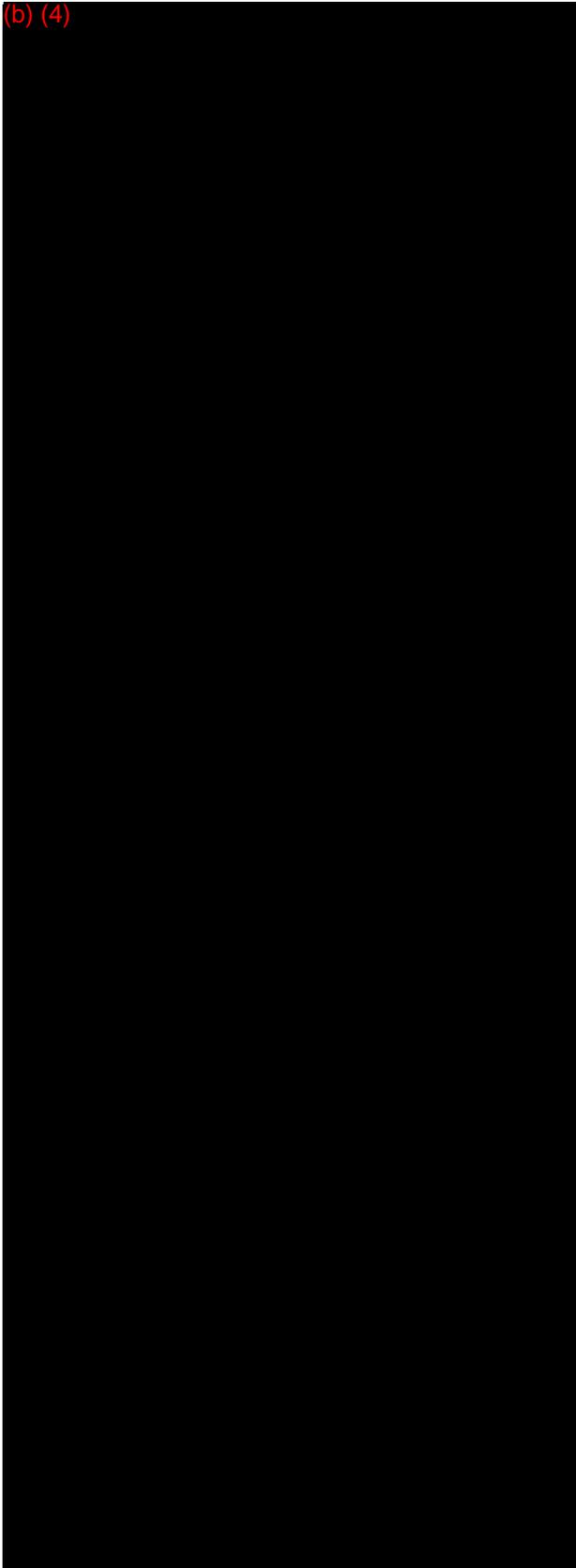


EXHIBIT #12a

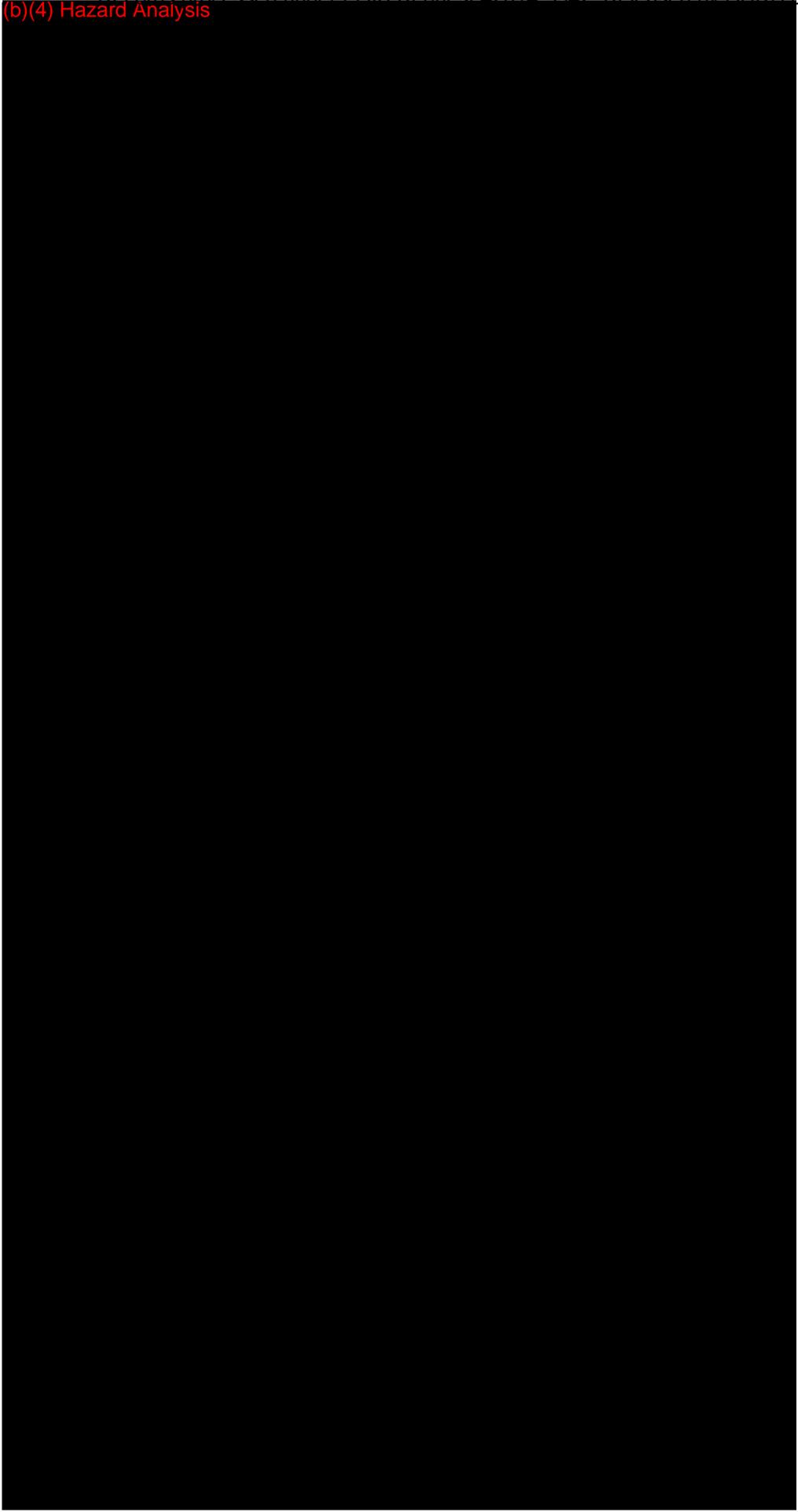
113

Prepared by Peter Pan

Checked by: Leo Ho

Approved by: Donny Lee

(b)(4) Hazard Analysis



Device Hazard Analysis according to ISO 14971: 2000

EXHIBIT #12b

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Device Model No. & Name	FR1DM1	O: Occurrence	Degree 1-10
System Function	Forehead temperature measurement	S: Severity	Degree 1-10
Prepared by	Microlife corporation	D: Detection	Degree 1-10

(b)(4) Hazard Analysis

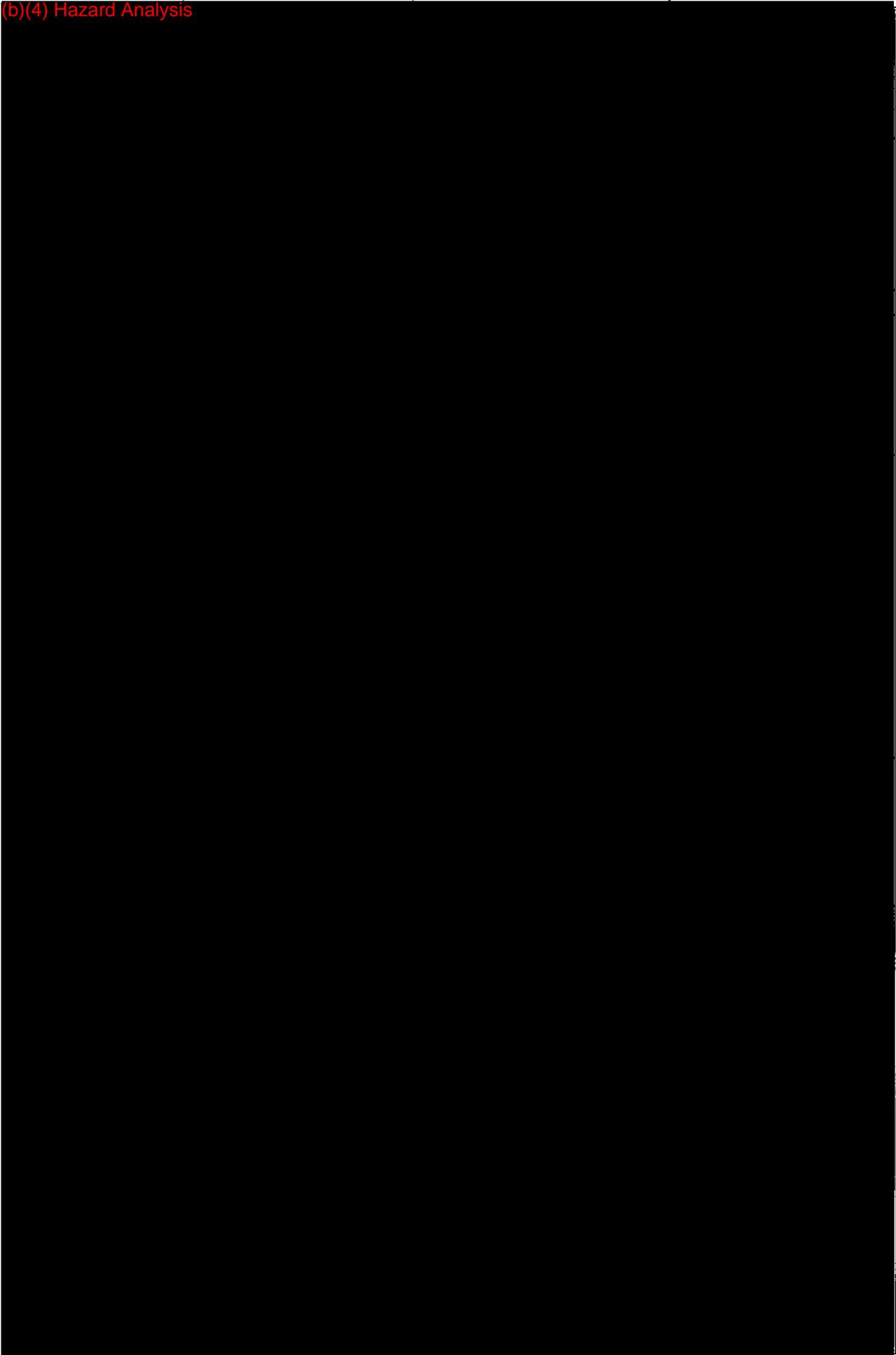


EXHIBIT #12b

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(b)(4) Hazard Analysis



EXHIBIT #12b

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EXHIBIT #14

LABEL AND MARKINGS			
Model name	FR1DM1	Issue date	2003.09.29
Product name	Infrared Forehead thermometer	Version	00
Label			
Approved by :	Donny Lee	Checked by	Ted Hu
		Drawn by	Liu Li Hong



Microlife Infra red Forehead Thermometer Software Specification

V1.0

Approved by:	Checked by:	Written by:
George Chi	Donny Lee	Leo Ho



Table of Contents

Items:

A. Level of Concern

B. Software Description

C. Device Hazard Analysis

D. Software Requirement Specification (SRS)

E. Architecture Design Chart

Software Test Report	
Product Name: Infra red Forehead thermometer	Page 1
Model Name: FR1DM1	2003/08/14



**Infra red Forehead thermometer FR1DM1
Software Validation Report**

Tested by:	Checked by:	Approved by:
Jeashion Yang	Colin Lin	Colin Lin

Software Test Report	
Product Name: Infra red Forehead thermometer	Page 2
Model Name: FR1DM1	2003/08/14

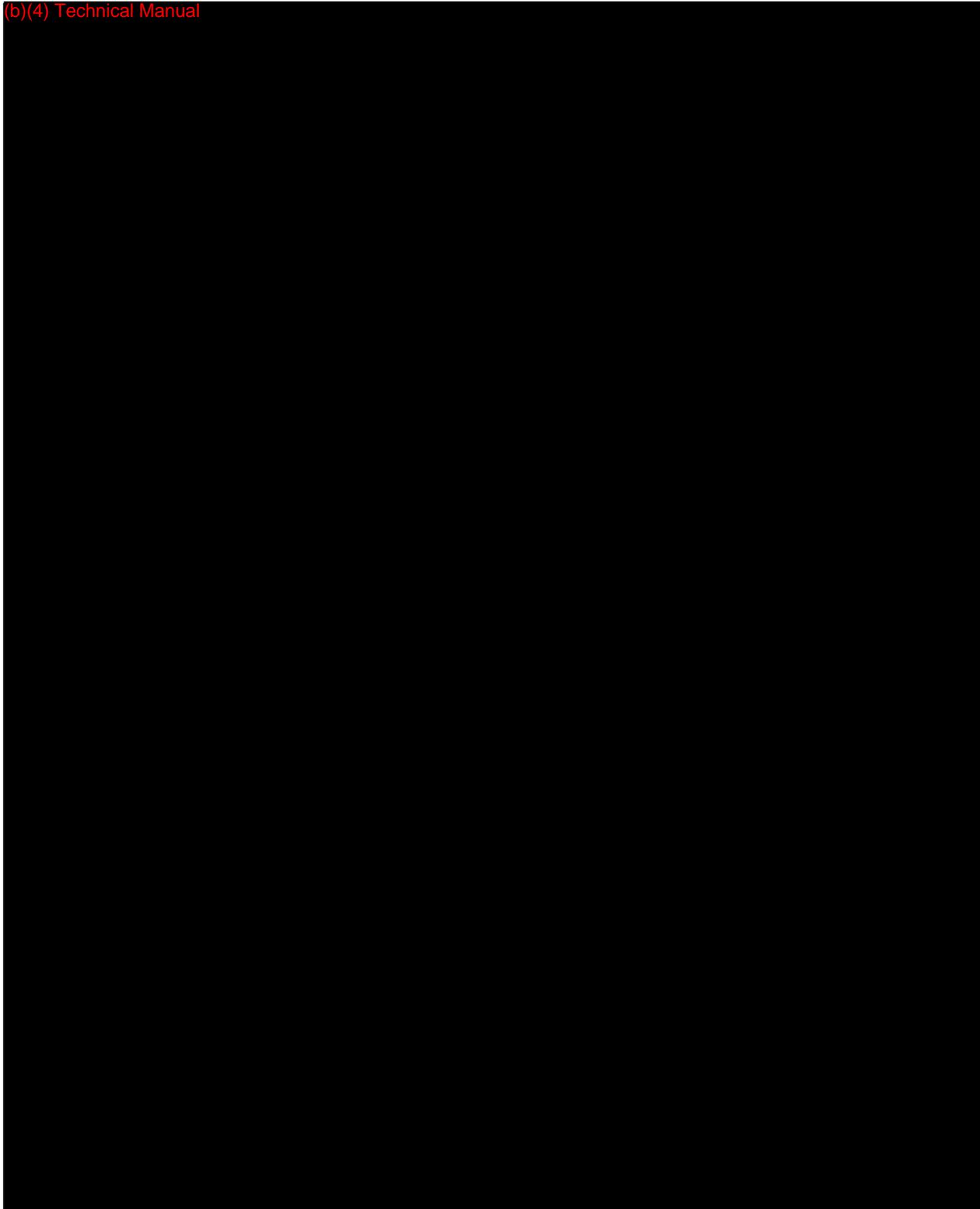
Contents

- A. Specification**
- B. Operation sequence and LCD display**
- C. Accuracy verification**

EXHIBIT #17

FR1DM1 technical manual

(b)(4) Technical Manual

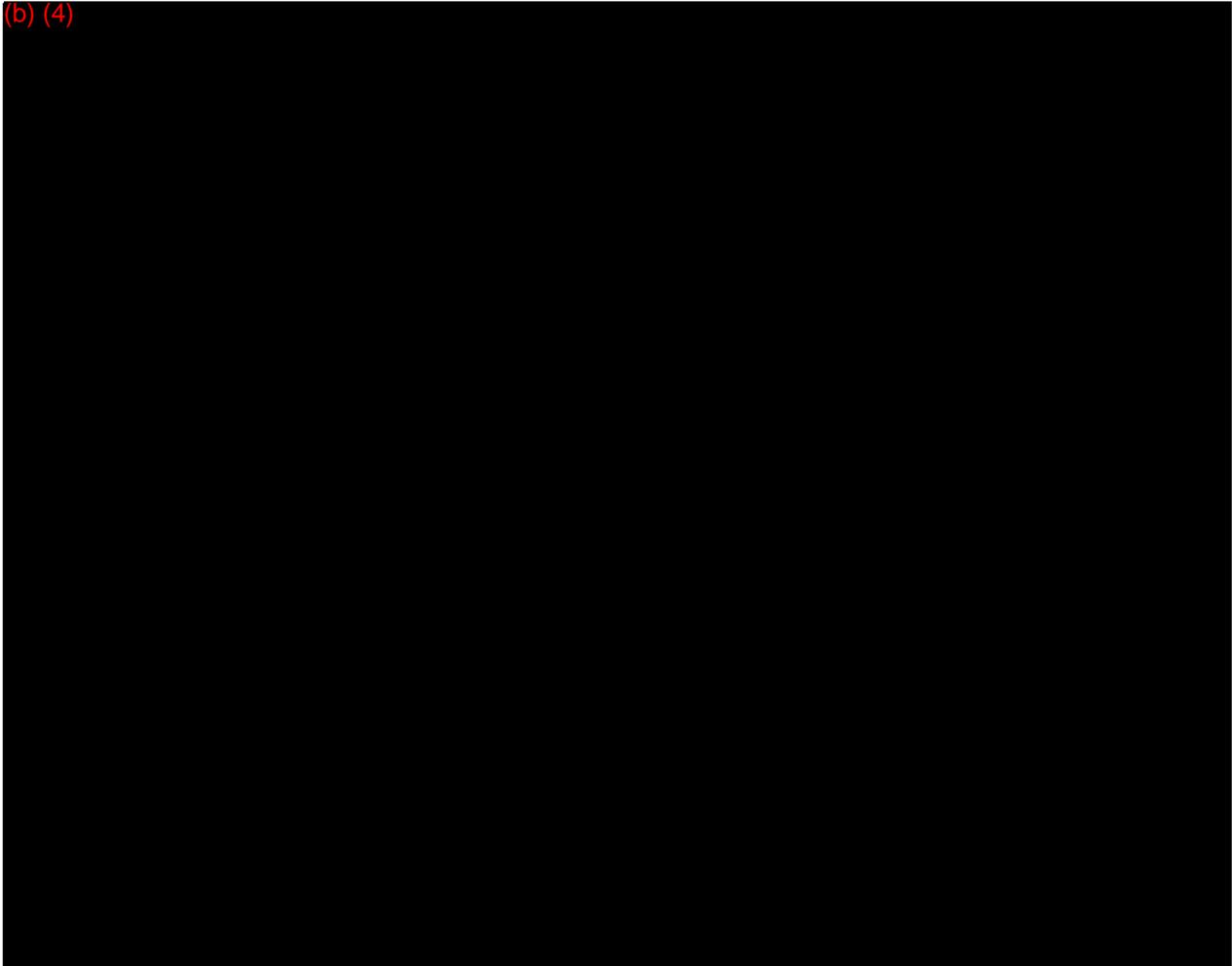


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To whom it may concern:

Declaration of Identity

(b) (4)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

12/19/03

From: Reviewer(s) - Name(s) Erika Jordan

Subject: 510(k) Number K033820

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 d

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

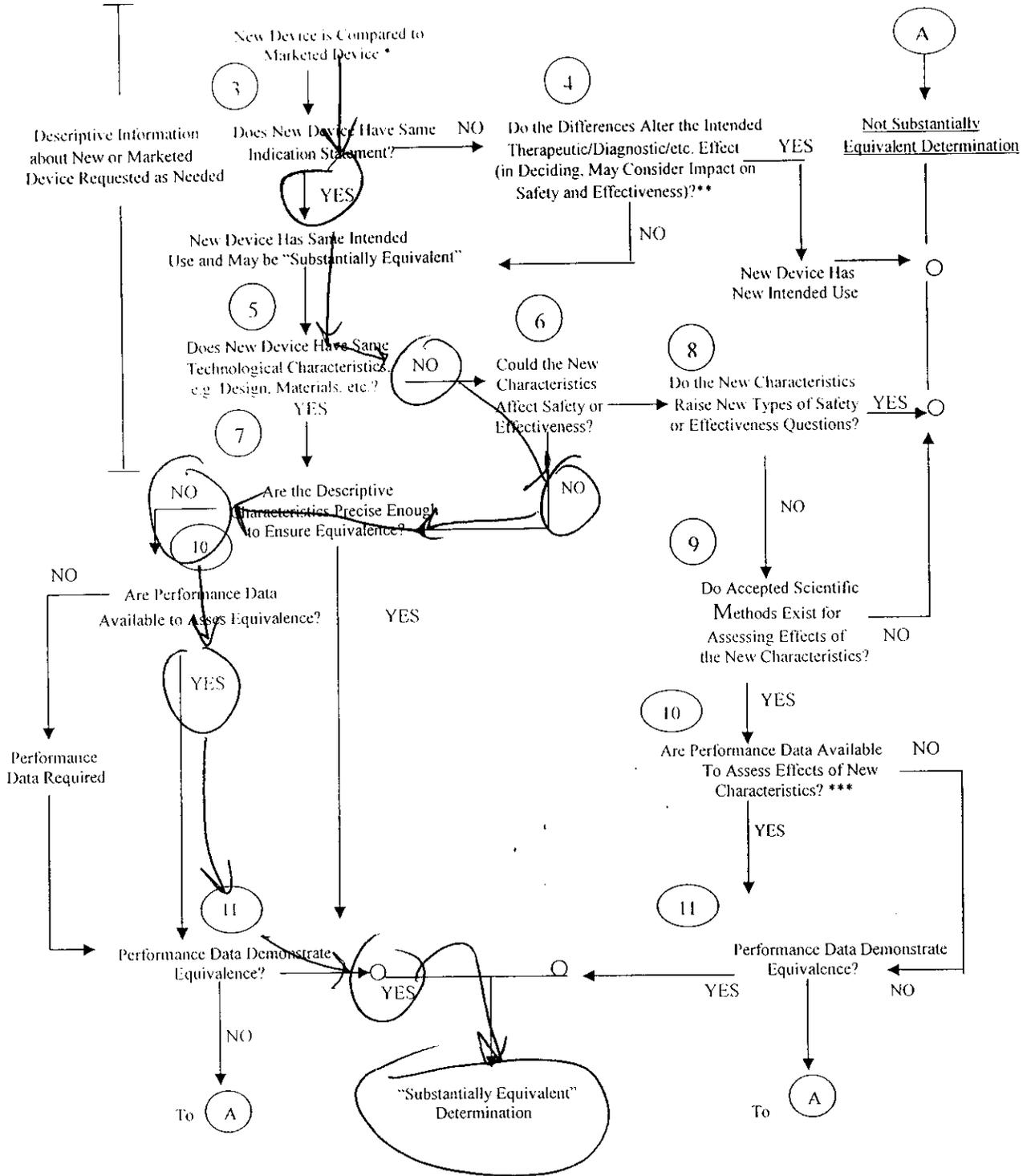
80 FULL Class II 880.2910

Review: [Signature] (Branch Chief) _____ (Branch Code) 2/23/04 (Date)

Final Review: [Signature] _____ (Date) 2/23/04

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K033820

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1; 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

is posted with the 510(k) boilers on the H drive.)		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	<i>non-sterile</i>	
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method	✓	
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: 479

Concurrence by Review Branch: DEC 19 2014

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K033820

Reviewer: Erika Jordan, Biomedical Engineer

Division/Branch: DAGID/GHDB

Device Name: Microlife Digital Infrared Forehead Thermometer, Model FR1DM1

Product To Which Compared (510(K) Number If Known): K020725

YES NO

1. Is Product A Device	Y		If NO = Stop
2. Is Device Subject To 510(k)?	Y		If NO = Stop
3. Same Indication Statement?	Y		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		N	If YES = Stop NE
5. Same Technological Characteristics?		N	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		N	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		N	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	Y		If NO = Request Data
11. Data Demonstrate Equivalence?	Y		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See Review Memo dated 2/17/04.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics: *This thermometer takes temperature measurements from the forehead instead of the ear as the predicate does.*
6. Explain how new characteristics could or could not affect safety or effectiveness: *There are previously cleared infrared forehead thermometers on the market. This is not a novel technology.*
7. Explain how descriptive characteristics are not precise enough: *Descriptive characteristics are not precise enough to show the accuracy and reliability of this device.*
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *The performance data demonstrates the safety and effectiveness of this device. Accuracy, electrical safety, and reliability were determined by the tests and performance data.*

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?	✓	✓
5. Is the product a device?		✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?		✓
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		✓
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓

MEMO TO THE RECORD
510(K) REVIEW

K033820

DATE: 02/17/04
FROM: Erika Jordan

OFFICE: ODE (HFZ-480)
DIVISION: DAGID/GHDB

COMPANY NAME: Microlife Intellectual Property
DEVICE NAME: Microlife Digital Infrared Forehead Thermometer, Model
FR1DM1

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is an electronic thermometer using an infrared sensor (thermopile) to measure forehead temperature, then get a reading and display it on an LCD. Its operation is based on measuring the natural thermal radiation emanating from the forehead and the adjacent surfaces.

2. INTENDED USE:

The Microlife Digital Infrared Forehead Thermometer, Model FR1DM1 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

3. DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: No
- B. Implant (short-term or long-term): No
- C. Is the device sterile? No
- D. Is the device for single use? No
- E. Is the device for prescription use? No
If yes, is prescription labeling included? N/A
- F. Is the device for home use or portable? Yes
Whether the answer is yes or no, is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary? Yes
- G. Does the device contain drug or biological product as a component?
No
- H. Is this device a kit? No
- I. Software-driven: Yes
Estimated level of concern: (Major, Moderate, Minor)? Minor
Has the firm provided a hazard analysis, software requirements and

Page 2 of 510(k) review

design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices? Yes

- J. Electrically Operated: Yes
 If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided? Yes
- K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):

IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety

IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety: Electromagnetic Compatibility

ASTM E1965 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

ISO 10993 Biological Evaluation of Medical Devices

If applicable, has test data been provided to demonstrate conformance (protocol, data, and results)? Yes

- L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:

MicroLife Ear Thermometer, Model IR1DE1, K020725, MicroLife Corporation

- M. Submission provides comparative specifications
- | | |
|----------------------------------|------------------|
| a. Yes | b. No |
| comparative in <u>vitro</u> data | performance data |
| c. Yes | d. Yes |
| animal testing | clinical testing |
| e. Yes | f. Yes |
| biocompatibility testing | |

- N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Item	MicroLife IR1DE1 (predicate)	MicroLife FR1DM1
Thermometer type	Infrared Ear thermometer	Infrared Forehead thermometer
Intended Use	Intermittent measurement of human body temperature in the home.	Intermittent measurement of human body temperature in the home.
Labeling	MicroLife IR1DE1 Thermometer	MicroLife FR1DM1 Thermometer
Components	IR Thermopile sensor, ASIC, E ² PROM IC, LCD and Backlight, Key * 2, Buzzer * 1	IR Thermopile sensor, ASIC, E ² PROM IC, LCD and Backlight, Key * 2, Buzzer * 1

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Signal processing and Display	IR sensor → Amplifier → A/D → Microprocessor → LCD	IR sensor → Amplifier → A/D → Microprocessor → LCD
Power Requirements	CR2032, 1.5 V Battery *1	CR2032, 1.5V Battery *1
Displayed Temperature Range	32 ~ 42.2 °C (89.6 ~ 108 °F)	34~42.2 °C (93.2 ~ 108 °F)
Operating Ambient Temp. Range	5 ~ 40 °C (41 ~ 104 °F)	16 ~ 40 °C (60.8 ~ 104 °F)
Storage Ambient Temp. Range	-25 ~ +55 °C (-13 ~ 131 °F)	-25 ~ +55 °C (-13 ~ 131 °F)
Display Resolution	0.1 °C or °F	0.1 °C or °F
Accuracy for display Temp. Range	± 0.2 °C (32 ~ 42.2 °C)	± 0.2 °C (34 ~ 42.2 °C)
Battery Life	1 yr/1000 measurements	1 yr/1000 measurements
Memory	1 set, last measurement	12 sets, last measurement
Response time	Normal mode 1 sec	Normal mode 1 sec
Low/Dead Batter Warning	Low Battery: 2.7 V Dead Battery: 2.6 V	Low Battery: 2.7 V Dead Battery: 2.6 V
Fever alarm	Yes	Yes
Power Auto Off	1 min., after last operation	1 min. after last operation
Offset	No	Yes
Probe cover	Yes	No
Read Site	Tympanic	Forehead
Display Type	LCD	LCD
Back light	Yes	Yes
Sensor type	Thermopile	Thermopile

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? If not, does the submission include a certification that such information will be made available to interested persons upon request? Yes

P. RECOMMENDATION:

I believe that this device is equivalent to: 80 FLL

Classification should be based on:

880.2910 Class: II

Erika F. Jordan
 Erika F. Jordan
 Biomedical Engineer

WMB, Interim BC
 2/22/04

FAX TRANSMISSION

PLEASE DELIVER THE FOLLOWING PAGES

TO: Ms. Erika Jordan
NAME

FOA - DAHD/OOE/CDRH
COMPANY

301-480-3002
FAX NUMBER

FROM: SUSAN GOLDSTEIN-FALK
NAME

mdi Consultants, Inc.
COMPANY

480-614-3169 K# 033820
FAX NUMBER

TOTAL PAGES: 3 (incl. C/P)

TODAY'S DATE: 2/20/04

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL US AS SOON AS POSSIBLE (480-451-7502)

COMMENTS: Dear Erika -

As discussed: the technical

specification page of the

submission, showing the

(b) (4)



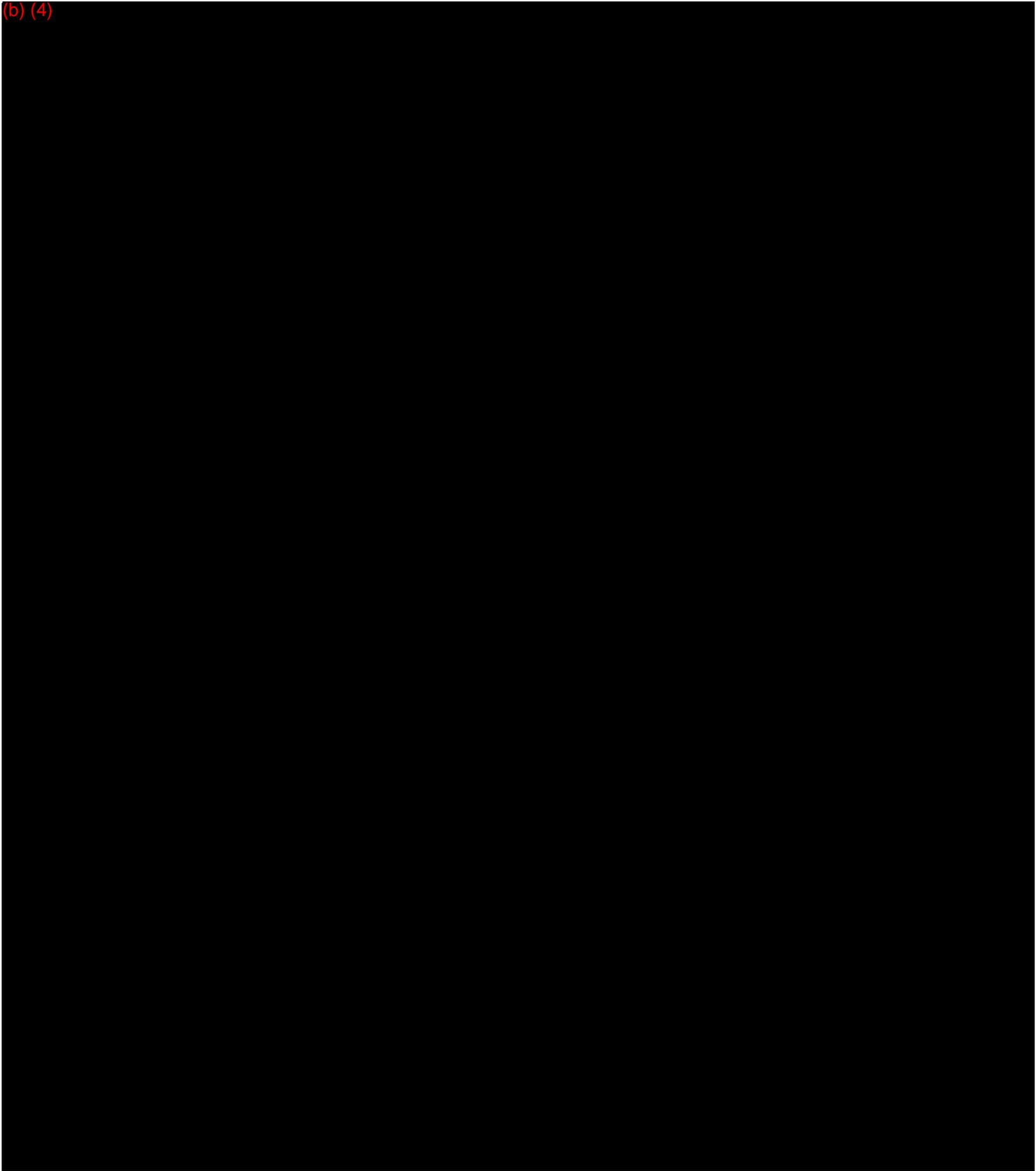
Thanks -

Susan D. Goldstein-Falk



Specification

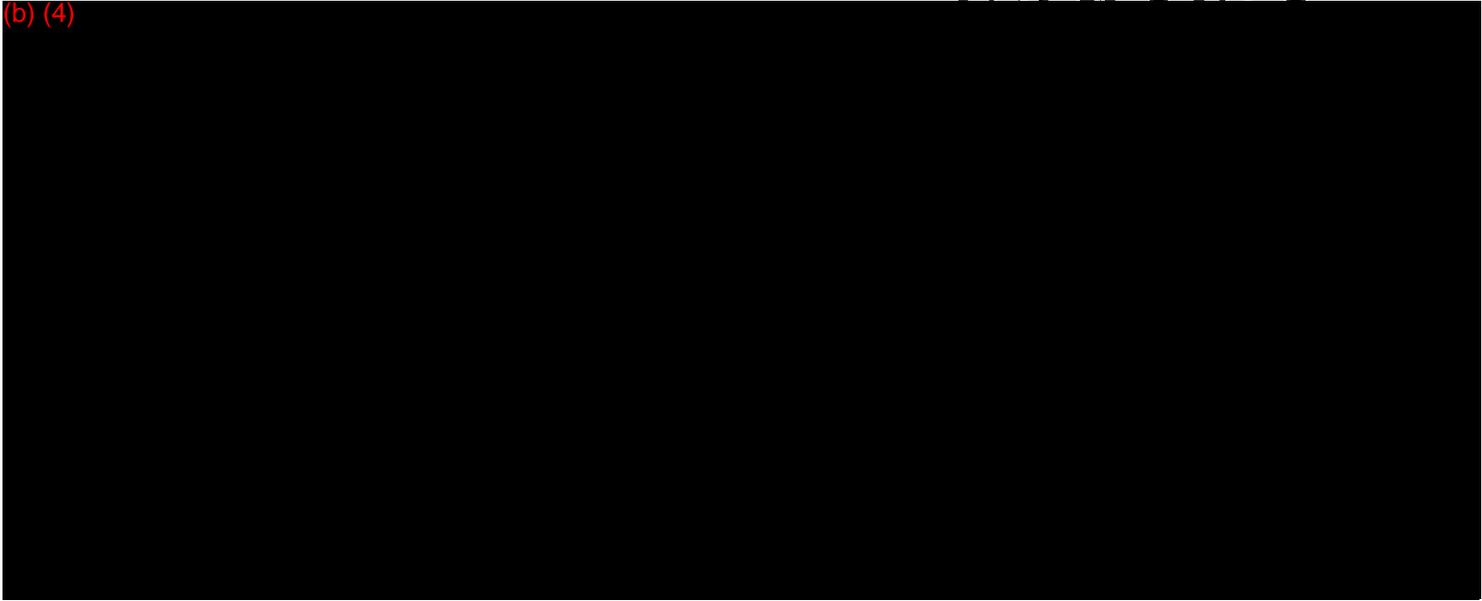
(b) (4)



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microlife

(b) (4)



The following questions outlined in the DCRND 510(k) Guidance Format are answered as follows:

1. Is the device life supporting or life sustaining?

No

2. Is the device an implant?

No

3. Is the device sterile?

No

4. Is the device single use or reusable?

Reusable

5. Is the device for prescription use?

No

6. Is the device for hospital, home, or mobile use?

Home Use

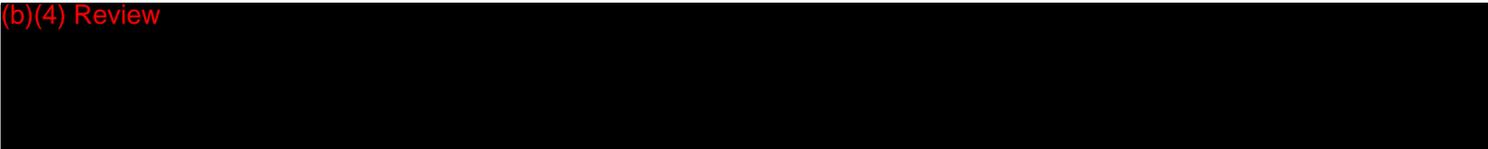
7. Does the device contain a drug or biological product as a component?

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Jordan, Erika F

From: Jordan, Erika F
Sent: Friday, February 20, 2004 10:42 AM
To: 'Susan Goldstein-Falk'
Subject: RE: Microlife K#033820, Microlife Digital Infrared Forehead Thermometer

(b)(4) Review



Thanks,
Erika

Erika F. Jordan
Biomedical Engineer
U.S. Food and Drug Administration
General Hospital Device Branch/DAGID/ODE/CDRH
9200 Corporate Blvd. (HFZ-480)
Rockville, MD 20850
Email: Erika.Jordan@fda.hhs.gov
Phone: (301) 594-1287 ext. 177
Fax: (301) 480-3002

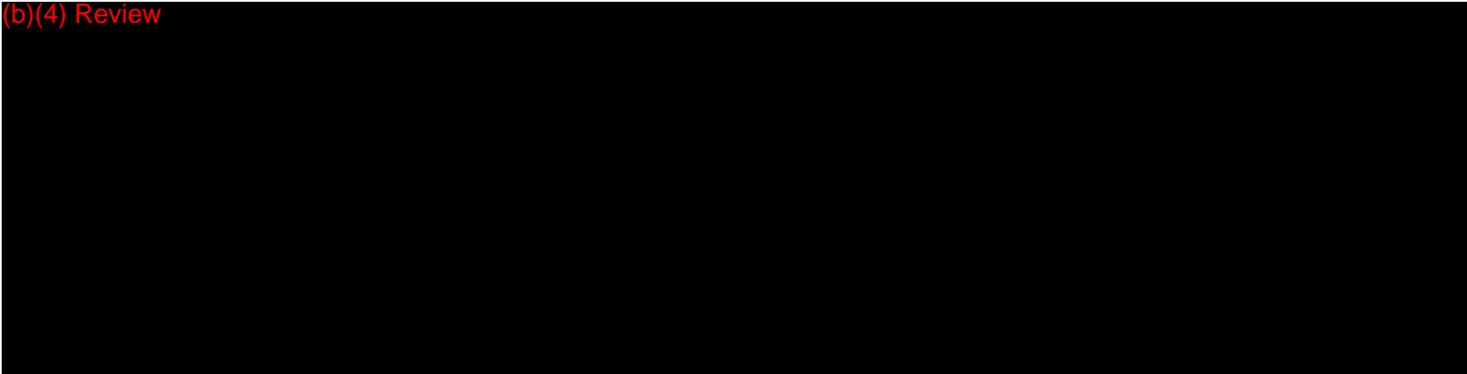
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.

-----Original Message-----

From: Susan Goldstein-Falk [mailto:sgoldstein@mdiconsultants.com]
Sent: Thursday, February 19, 2004 1:13 PM
To: Jordan, Erika F
Cc: Linda O'Brien
Subject: Microlife K#033820, Microlife Digital Infrared Forehead Thermometer

Dear Erika:

(b)(4) Review



Any questions, please contact me at 480-451-7502.

Regards,

Susan D. Goldstein-Falk
Official Correspondent for Microlife

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**Microlife Intellectual Property
Max Schmidheiny-Strasse 201
9435 Heerbrugg
Switzerland**

Tel: +41717277000 Fax: +41717277059

FAX TRANSMISSION

TO: Ms. Erica Jordan
FDA, ODE Reviewer
Fax: 301-480-3002
Tel: 301-594-1287 x 177

FROM: Ms. Susan D. Goldstein-Falk
Official Correspondent for Microlife
Phone # 480-451-7502
Fax # 480-614-3169

DATE: February 18, 2004

NO. OF PAGES: 2 (Including this page)

REF: 510(k) #033820
Microlife Digital Infrared Forehead Thermometer
Model FR1DM1
Dated: December 8, 2003
Received: December 9, 2003

Dear Ms. Jordan:

(b) (4)

If you have any questions, or require additional information, please feel free to call me at 480-451-7502 or FAX me at 480-614-3169.

Sincerely,

Susan D. Goldstein-Falk
Official Correspondent for
Microlife Intellectual Property, GmbH
SDG-F/lo

Attachment

- When one beep is heard (and the temperature still is flashing), place the probe tip at the center of forehead. Make sure the opening of probe is contacted closely with the skin.
- Press the Start button for 1 second and keep the probe at the forehead until the thermometer generates a long beep to identify the completion of the measurement.

The Microline Digital Infrared Forehead Thermometer (FR1DM1) has been clinically tested and proven to be safe and accurate when used in accordance with the operating instruction manual.

5. Control Displays and Symbols

LCD Display	Display Meaning	Description
	All segments displayed	Press the Off button to turn on the unit, all segments will be shown for 2 seconds.
	Memory	The last reading will be shown on the display automatically for 3 seconds.
	Ready	The unit is ready for the measurement, the °C or °F box will keep flashing.
	Measurement complete	The reading will be shown on the LCD display with the °C or °F box flashing for 10 seconds.
	Low battery indication	When the unit is recharged on the battery, the unit will keep flashing to remind the user to replace the battery.

8. Directions for Use
1. Press the On button, the LCD is activated to show all segments for 2 seconds.
 2. The measurement reading will be shown on the display automatically for five seconds with the °F box.
 3. When the °C or °F box is flashing, a beep sound is heard and the thermometer is ready for the measurement.
 4. Place the probe at the center of forehead. Make sure the opening of probe is completely contacted with the skin of forehead.
 5. Press the "START" button. Release it when you hear a beep sound. This is the emitting signal that confirms the end of measurement.
 6. Remove the thermometer from the forehead. The LCD displays the measured temperature.

NOTE: 10 short beeps will sound when the temperature is higher than 37.5°C in order to alert the patient that the table may have fever.

7. In order to assure the accurate readings, please wait at least 10 seconds after 1-5 on its aus measurements.

NOTE:

- Always take the temperature in the same location, since the temperature readings may vary from different locations.
- In the following situations, it is recommended that three to four positions in the same location at five second intervals and the highest one taken as the reading.
 - 1) New born infants in the first 100 days.
 - 2) Children under three years of age with a compromised immune system and for whom the precise accuracy of fever is critical.
 - 3) When the user is having any trouble using the thermometer for the first time, the unit helps the user to familiarize themselves with the thermometer and obtains consistent readings.
- 7. Changing from Fahrenheit to Celsius and vice-versa: The Microline Digital Infrared Forehead Thermometer (FR1DM1) can display temperature measurements in either Fahrenheit or Celsius. To Change

Memorandum

To: File
From: Erika Jordan, Reviewer *WJ*
Date: 2/17/2004
Re: K033820 Microlife Digital Infrared Forehead Thermometer, Model FR1DM1

(b) (4)



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