

2/25/99

II. 510(k) Summary  
[As described in CFR §807.92]

Submitted by: Micro Idea Instrument Co., LTD.  
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Shih-lin District  
Taipei, 11154 China (Taiwan)

Contact Person: Gerhard Frick  
Regulatory Manager ML Group

Date Prepared: 12/16/98

Proprietary Name: Microlife IT2CA1

Common Name: Thermometer, Electronic Thermometer, Predictive Thermometer

Classification Name: Class II §880.2910 Clinical Electronic Thermometer  
(To be manufactured and marketed for Consumer home use)

Predicate Device: SureTemp®  
Welch Allyn, Inc.  
510(k) Document Control Number K943695

Description of the Device:

The MicroLife IT2CA1 Digital 4-Sec Predictive Thermometer is the first predictive "Consumer Version" of the clinical thermistor thermometer for use in adults and children. Consumer thermometers currently available do not utilize the predictive technique, and acquire oral and axillary temperature in the standard mode, in which the measurement period is approximately one minute. The IT2CA1 consumer version 4-Sec predictive thermometer, embodies the predictive algorithm of the SureTemp® from Welch Allyn, San Diego, which provides a safe, simple, rapid and accurate method for determining clinical temperature using the traditional body sites and proven technology.

The IT2CA1 can be used in either "Rapid" (predictive) mode or "Normal" mode. In Normal mode, the IT2CA1 indicates the actual temperature sensed by the thermistor in the probe. In Normal mode, the measurement ends when temperature rise is  $<0.1^{\circ}\text{C}/25$  sec. In the Rapid mode, the IT2CA1 uses an algorithm to calculate the temperature that the thermistor in the probe would eventually reach (converge to) if it remained in place (in the patient's body). In the Rapid mode, as the probe temperature gets closer to the patient's sublingual (under the tongue), or axillary temperature, the decreasing temperature difference between the probe and the patient causes the rate that the

probe warms to decrease. The changes in the probe temperature enable the predictive algorithm to calculate the temperature at which the probe would stop being warmed by the patient (when it reaches the temperature of the patient). The IT2CA1 minimizes the amount of time the probe must be in the patient before the algorithm can calculate the "predicted" final temperature, through the use of the temperature-sensing probe which features the traditional thermistor technology and the predictive algorithm of the SureTemp® from Welch Allyn, San Diego. The minimization of time reduces patient immobilization and discomfort is minimized while the convenience for the home user is maximized.

The device assembly is made of acrylonitrile butadiene styrene (ABS), Cicolac-T grade or equal. The sensor measures the temperature of the probe tip. It is a negative temperature coefficient ceramic sensing elements, which has leads bonded and then encapsulated in an epoxy-filled polyamide tube. This assembly process renders the sensor hermetically sealed from possible environmental contamination. The resistive warming element within the probe plays a role in enabling the rapid oral temperature determination. Prior to each use, the probe of the IT2CA1 must be covered by a disposable low density polyethylene (LDPE) plastic probe cover that does not significantly reduce the transfer of heat from the patient to the probe body and thermistor. The disposable probe cover prevents microbiological cross-contamination among patients which might occur with a reusable probe cover. The disposable probe covers will be manufactured by Welch Allyn, San Diego. A complete list of features and characteristics for the IT2CA1 have been provided in Table 1.

Intended Use of the Device:

The IT2CA1 thermometer has the same intended use as the predicate device. The device is used in the determination of a febrile, or afebrile patient temperature, in either rapid mode(4-sec. Predictive temperature), or standard/monitor mode(actual determination of temperature). The IT2CA1 differs from the predicate device with regards to user environment. The predicate device is utilized in a clinical environment, while the IT2CA1 provides the home user with the ability to determine temperature.

The IT2CA1 is intended for lay or home use only; in a home use environment. It is not intended for use by the clinical professional, such as those utilized in the hospital, clinical, or mobile environment use.

Technological Characteristics:

The IT2CA1 utilizes the same temperature-sensing probe which utilizes the traditional thermistor technology and the predictive algorithm of the SureTemp® predictive clinical electronic thermometer. The following table summarizes the similarities and differences between the IT2CA1 and the predicate device.

Table 1

Specifications & Technological Comparison Between the Microlife IT2CA1 & the Welch Allyn SureTemp®

	MicroLife IT2CA1	Welch Allyn SureTemp®
Type	Instant - Home Use	Instant - Clinical
Device Technology	Thermistor in Probe	Thermistor in Probe
Probe	Thermal Design Warmer Circuitry	Thermal Design Warmer Circuitry

*Microlife IT2CA1 Premarket Notification*

Software	Predictive Algorithm	Predictive Algorithm
Accuracy	±0.2 °F (±0.1 °C)	±0.2 °F (±0.1 °C)
Technical measuring accuracy	In normal (standard) mode <sup>1</sup> and in water bath: ± 0.1°C	In monitor mode <sup>2</sup> and in water bath: ± 0.1°C
Temperature Measurement Range	84°F (28.9°C) - 108°F (42.2°C)	84°F (28.9°C) - 108°F (42.2°C)
Measuring Modes		
Oral	Normal or Rapid (Predictive)	Monitor or Normal (Predictive)
Axillary	Normal or Rapid (Predictive)	Monitor or Normal (Predictive)
Rectal	NA	Monitor or Normal (Predictive)
Display	LCD with indicating unit 0.1°C	Custom LCD
Acoustic	Indicates readiness for measurement	Indicates readiness for measurement
Low Battery Indicator	Yes	Yes
Number of readings stored in Memory	Display of temperature last measured	Display of temperature last measured
Unit Dimensions		
Height	23mm	57.15 mm
Width	35mm	76.2 mm
Length	203mm	177.8 mm
Weight	55g (without batteries)	318.9 g
Operating Environment	+10°C to +40°C	+15°C to +40°C
Humidity Range	15% to 95%, non-condensing	15% to 95%, non-condensing
Storage Environment	-4F° (-20°C) to 120F° (50°C)	-4F° (-20°C) to 120F° (50°C)
Storage Humidity Range	15% to 95%, non-condensing	15% to 95%, non-condensing
Power Source	3 AAA Alkaline Batteries	3 AA Alkaline Batteries
Battery Life	Approximately 3500 readings	Approximately 5000 readings
Internal Diagnostic Tests	Yes	Yes
Power Up Test of Key Circuits	Yes	Yes
Power Up Test of Heater Fail Safe Circuit	Yes	Yes
Mounting Configuration	NA	Various Mounting Applications
Case Material	ABS Plastic	ABS Plastic
Probe cover material	Polyethylene	Polyethylene
Automatic Switch off	30 seconds after end of measurement in rapid mode, 10 minutes after end of	No

<sup>1</sup> Rapid Mode: 4-Sec. Predictive Instant Thermometer.

Normal Mode: Maximum Thermometer (measurement ends when temperature rise is <0.1°C/25 sec).

<sup>2</sup> Normal Mode: 4-Sec. Predictive Instant Thermometer.

Monitor Mode: Continuous actual temperature readings sensed by the thermistor in the probe.

*Microlife IT2CA1 Premarket Notification*

	measurement in standard mode	
Standards	Complies with ASTM requirements E1112-86 "Clinical Test Standard", prEN12470-3:1997	Complies with ASTM requirements E1112-86 "Clinical Test Standard"
Warranty	Two Years	One Year



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 25 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Microlide Systems AG  
C/O Mr. Gerhard Frick  
Regulatory Manager ML Group  
Micro Idea Instrument Co. Ltd.  
7F, NO.361, TA-NAN Road  
Shih-lin District  
Taipei, 11154 China (TAIWAN)

Re: K990168  
Trade Name: Microlife IT2CA1  
Regulatory Class: II  
Product Code: FLL  
Dated: December 16, 1998  
Received: January 19, 1999

Dear Mr. Frick

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

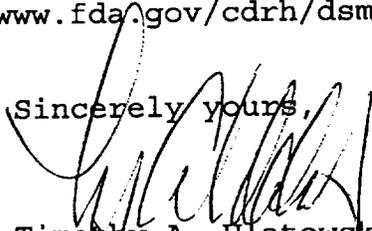
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## VII. Indications for Use Statement

510(k) Number: Unknown

Device Name: Microlife IT2CA1 Electronic Intermittent Thermometer

Indications for use: The IT2CA1 is used in a home use environment to make an accurate prediction of a febrile, or afebrile compliant patients oral temperatures after a measurement time (in the sublingual pocket) of only 4 seconds, and axillary temperatures in approximately 10 seconds in the Rapid mode. In Normal mode, the IT2CA1 provides accurate determination of actual, oral and axillary temperatures of compliant patients.

The IT2CA1 is intended for lay or home use only; in a home use environment. It is not intended for use by the clinical professional, such as those utilized in the hospital, clinical, or mobile environment use.

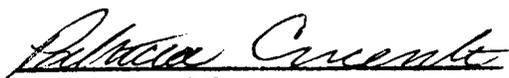
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ Or Over-The-Counter Use

(Per 21 CFR §801.109)



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

510(k) Number K990148