

K972259

EXHIBIT #1

JUL 10 1997

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:

Micro Weiss Electronics
89 Bell Street
W. Babylon, NY 11704
Contact: Mr. John Weiss

Date Summary Prepared: June 13, 1997

2. Name of the Device:

Pro Check™ Digital Pacifier Thermometer

3. Predicate Device Information:

1. The Pasi-Temp Pacifier Digital Thermometer, K#952073, Intelligent Product Ltd. Co., Orem, Utah (presently owned by Acute Ideas Co., Ltd.)

2. The Basis® Baby-Temp Pacifier Digital Thermometer, K#962991, Polymedica Industries, Inc., Golden, Colorado.

4. Device Description:

The Pro Check™ Digital Pacifier Thermometer, is a battery-powered, liquid crystal display device using a thermometer embedded in the nipple. The patient contact portion is composed of medical silicone rubber. The body is of ABS plastic. This device is reusable and no components are disposable. This device is not intended for use with other sheaths or devices.

EXHIBIT #1

5. Intended Use:

The Pro Check™ Digital Pacifier Thermometer, is a non-sterile, re-usable clinical thermometer intended for the determination of oral body temperature in infants to children five years of age.

6. Comparison to Predicate Devices:

The Pro Check™ Digital Pacifier Thermometer, is identical to the Pasi-Temp Pacifier Digital Thermometer and the Basis® Baby-Temp Pacifier Digital Thermometer.

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

The Pro Check™ Digital Pacifier Thermometer, conforms to physical requirements and operating parameters outlined in ASTM #1112, "Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature". It also meets EPA requirements for nitrosamines and Consumer Product Safety Commission (CPSC 1511) requirements by Baby Pacifiers (choking hazards).

8. Discussion of Clinical Tests Performed:

Clinical testing previously performed for the Pasi-Temp and Basis® Temp Pacifier Digital Thermometer also apply to the Pro Check™ Digital Pacifier Thermometer.

9. Conclusions:

The Pro Check™ Digital Pacifier Thermometer, is identical in intended use, design, material and technology as the Pasi-Temp and Basis® Temp Pacifier Digital Thermometers. Thus, when compared to the predicate devices, the Pro Check™ Digital Pacifier Thermometer, does not incorporate any changes in intended use, method of operation, material or design that could affect safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susan Goldstein-Falk
Official Correspondent
Micro Weiss Electronics
C/O MDI Consultants, Incorporated
55 Northern Boulevard, Suite 410
Great Neck, New York 11021

JUL 10 1997

Re: K972259
Trade Name: Pro Check Digital Pacifier Thermometer
Regulatory Class: II
Product Code: FLL
Dated: June 13, 1997
Received: June 17, 1997

Dear Ms. Goldstein-Falk:

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.

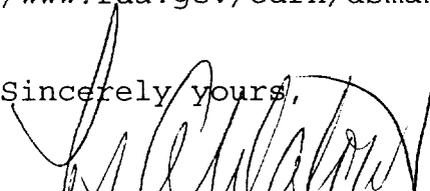
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

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) 594-4618. 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

510(k) Number (if known): _____

Device Name: Pro Check™ Digital Pacifier Thermometer

Indications For Use:

The Pro Check™ Digital Pacifier Thermometer, is a non-sterile, re-usable clinical thermometer intended for the determination of oral body temperature in infants to children five years of age.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Patricia Cuervo*
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K912259

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)