NOV 19 2004

K042906(p. 1 of 3)

Exhibit #1

510(K) SUMMARY

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

The assigned 5l0(k) number is:_____.

1. **Submitter's Identification:**

AMPLIFE Corporation
10F, No. 69, Sec. 3, Hue Jung Rd
Taichung, Taiwan, R.O.C
Tel: +0422587766 Fax: +0422587558

Date Summary Prepared: September 23, 2004

Contact: Mr. Laurence Yang

2. **Name of the Device:**

AMPLIFE Digital Infrared Ear Thermometer, Model E100

Common Name or Classification Name:

Infrared Ear Thermometer/Clinical Electronic Thermometer

3. **Predicate Device Information:**

Microlife Intellectual Property GmBH Infrared Ear Thermometer, Model IR1DE1-1, K# 034023.

4. **Device Description:**

The AMPLIFE Digital Infrared Ear Thermometer, Model E100 is a digital infrared Ear Thermometer (without probe cover) using an infrared sensor (thermopile) to measure eardrum temperature, then get a reading and display it on the LCD.

Its operation is based on measuring the natural thermal radiation emanating from the eardrum.

The AMPLIFE Digital Infrared Ear Thermometer, consists mainly of five parts:

a) IR Thermopile Sensor
b) ASIC
c) E^2PROM IC

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

5. **Intended Use:**

The AMPLIFE Digital Infrared Ear Thermometer, Model E100, is a digital infrared Ear Thermometer (without probe cover) using an infrared sensor to detect body temperature from the ear in the neonatal, pediatric and adult population used in the home setting.

This device is used without a probe cover.

6. **Comparison to Predicate Devices:**

The AMPLIFE Digital Infrared Ear Thermometer, Model E100, is substantially equivalent to the Microlife Intellectual Property Digital Ear Thermometer, Model IR1DE1-1, which has the same intended use and is similar in design to the predicate device.

The AMPLIFE Digital Infrared Ear Thermometer, Model E100 and the predicate device are identical in functionality and performance with the difference being the external shape of the devices, and PCB layout of the devices, performance specifications, ergonomics of the user interface, dimensional specifications, The temperature measurements algorithm and its fundamental scientific technology are identical to the predicate device.

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 AMPLIFE Infrared Ear Thermometer E100. Clinical data was presented evaluating clinical bias, clinical uncertainty and clinical repeatability per AMPLIFE clinical test protocol for infrared Ear Thermometer.

K042906 (p. 3 of 3)

9. Conclusions:

The AMPLIFE Infrared Ear Thermometer, Model E100, has the same intended use and similar technological characteristics as the Microlife Intellectual Property Infrared Ear thermometer Model IR1DE1-1. 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 AMPLIFE Infrared Ear Thermometer, Model E100, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2004

AMPLIFE Corporation
C/O Ned Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue SE
Grand Rapids, Michigan 49548

Re: K042906
Trade/Device Name: AMPLIFE Digital Ear Thermometer E100
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 15, 2004
Received: November 17, 2004

Dear Mr. Devine:

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.

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 (240) 276-0115. 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

510(k) Number (if known): K042906

Device Name: AMPLIFE Digital Ear Thermometer E100

Indications For Use:

The AMPLIFE Digital Infrared Ear Thermometer, Model E100, is a Digital Infrared Ear Thermometer (without probe cover) using an infrared sensor to detect body temperature from the ear in the neonatal, pediatric and adult population used in the home setting.

The device is used without a probe cover.

Prescription Use _____ OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K042906