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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

Date Summary Prepared: November 29, 2004

Contact: Mr. Laurence Yang
Tel: 0422587766
Fax: 0422587558

2. **Name of the Device:**

AMPLIFE Upper Arm Blood Pressure Monitor, Model M100

Common Name or Classification:

Non-Invasive Blood Pressure Measurement System

3. **Predicate Device Information:**

The AMPLIFE Upper Arm Automatic Blood Pressure Monitor, Model M100 is substantially equivalent to the Microlife Automatic Blood Pressure Monitor, Model BP-2BHO, K# 970211.

4. **Device Description:**

The AMPLIFE Upper Arm Automatic Blood Pressure Monitor, Model M100 is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic semiconductor sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating

pulse rate, which is a well - known technique in the market called the "oscillometric method".

5. **Intended Use:**

The AMPLIFE Upper Arm Blood Pressure Monitor, Model M100 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

6. **Comparison to Predicate Devices:**

Both the subject and predicate devices use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. For the subject device, the cuff is inflated to a suitable pressure automatically without the need to pre-set the inflation pressure value by hand, as is the case with the predicate device; deflate rate is controlled, but a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units. The subject device, Model M100, uses a semiconductor pressure sensor instead of a capacitive pressure sensor (predicate device) to translate the pressure variations to electrical signals that can be interpreted by an integrating circuit. Once the reading is determined, each unit operates the linear valve to release the pressure to zero. In addition, the subject device has the added clock function which is not included in the predicate device.

Unlike the predicate device, the subject device, Model M100, uses a piezo-resistive pressure sensor to detect alternation of cuff pressure.

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

Testing information demonstrating safety and effectiveness of the AMPLIFE Automatic Blood Pressure Monitor, Model M100 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

a. General Functions Test
b. Reliability Test - Operation Conditions
c. Reliability Test - Drop Testing
d. Reliability Test - Storage
e. Reliability Test - Vibrating Testing

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f. EMC Test
g. IEC 60601-1 Safety Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the AMPLIFE Automatic Blood Pressure Monitor, Model M100 tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

We have performed the clinical test on AMPLIFE Upper Arm Blood Pressure Monitor according to "Clinical Data and Analysis ANSI/AAMI – SP-10 Standard, Section 4.4.2" which outlines and summarizes clinical testing performed.

9. Conclusions:

We have demonstrated that the AMPLIFE Automatic Blood Pressure Monitor, Model M100, is as safe and effective as the predicate, the Microlife Automatic Blood Pressure Monitor, Model BP-2BHO, based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and, the ANSI/AAMI Voluntary Standard, SP10-1992 testing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2005

AMPLIFE Corporation
c/o Mr. Ned Devine
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 43548

Re: K043550
Trade Name: AMPLIFE Upper Arm Blood Pressure Monitor, Model M100
Regulation Number: 21 CFR 870.1130
Regulation Name: Blood Pressure Monitor
Regulatory Class: Class II
Product Code: DXN
Dated: January 14, 2005
Received: January 18, 2005

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) 276-0120 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043550

Exhibit B

510(k) Number (if known): K043550

Device Name: AMPLIFE Upper Arm Blood Pressure Monitor, Model M100

Indications For Use:

The AMPLIFE Upper Arm Blood Pressure Monitor, Model M100, is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

Prescription Use _____		**Over-The Counter Use** _X_
(Per 21 CFR 801 Subpart D)	**OR**	**(21 CFT 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 Cardiovascular Devices
510(k) Number K043550