DEC 1 9 2003

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 870.92.

The assigned 510(k) number is: K033657.

1. Date Summary Prepared

November 19, 2003

2. Submitter's Identification

Living Data Technology Corporation
140 53rd Street
Brooklyn, NY 11232

Contact: Dr. Jun Ma
(718) 492-7400

3. Name of the Device

The Mobile External Counter Pulsation System AngioNew-V

4. Predicate Device Information

K023701, The Mobile External Counter Pulsation System AngioNew-IV
Living Data Technology Corporation, Brooklyn, NY

5. Device Description

The Mobile External Counter Pulsation System AngioNew-V is a mobile non-invasive external counter pulsation device for the treatment of patients suffering from congestive heart failure, stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock.

The Living Data Technology AngioNew-V system consists of a central control unit and three pairs of inflatable/deflatable cuffs that are wrapped respectively around a patient's calves, thighs and buttocks. External pressure is applied via the cuffs to the lower extremities of the patient in synchronization with the heartbeat. When the heart is in the relaxed state during diastolic period, pressure is applied sequentially from the distal to proximal extremities to force blood back to the heart, increase coronary perfusion pressure (diastolic augmentation) and, at the same time, increases coronary blood flow and enhances the development of

coronary collateral circulation. Just before the heart starts ejecting blood during systolic period, air is quickly withdrawn from all cuffs simultaneously to remove all the external applied pressure, leaving behind empty vasculature in the lower extremities to receive the output of the heart, thereby reducing systolic pressure (systolic unloading) and the workload of the heart.

6. Indications for Use

The Mobile External Counter Pulsation System AngioNew-V is a mobile non-invasive external counter pulsation device for the treatment of patients suffering from congestive heart failure, stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock.

7. Comparison to Predicate Device

The modified device AngioNew-V is essentially same in specifications as well as in technological and functional characteristics as the current device AngioNew-IV (cleared under K023701), except for the following technological upgrading:

- A control loop is added to the AC drive regulate the compressor motor for stabilizing the air reservoir pressure.
- A finger pulse plethysmography sensor is employed and the original temporal artery pressure sensor is optional now.
- The central control unit CPU is upgraded. The display is also upgraded from 9" CRT to 8.4" LCD.
- The quick connectors between cuffs and valves are improved with integrated senor to identify cuff connection sequence so that the machine adjusts inflation sequence accordingly, therefore adding an additional safety feature to the device.
- A new inflation timing adjustment method for better counter pulsation effect is used in AngioNew-V. Using a predetermined, heart rate dependent inflation timing as the initial value, the software updates the inflation timing to maximize counterpulsation effect.
- A finger oximetry sensor is added to provide measurement and display of blood oxygen saturation level.
- A built-in printer is added to the device to provide real time recording of ECG and pulse wave, as well as other information such as heart rate, D/S ratios, etc., during ECP treatment.

8. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence

In addition to safety tests in accordance with IEC 60601-1 and EN 60601-1; EMC tests in accordance with IEC 60601-1-2, EN 55011, EN 61000-3-2, and EN 61000-3-3; other testing was also conducted, such as:

- R-wave Detection and Heart Rate Calculation;
- Inflation/deflation Timing Control and Counterpulsation Effect;

etc.

It is concluded that AngioNew-V meets all safety and EMC requirement, as well as all design specifications. Therefore it is substantially equivalent to AngioNew-IV in safety and effect.

9. Conclusions

The subject device, AngioNew-V, has the same intended use and similar characteristics as the predicate device. Moreover, bench testing contained in our submission and non-clinical testing supplied demonstrate that there are no differences in their technological characteristics, thereby not raising any new questions of safety or effectiveness. Thus, the AngioNew-V device 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

DEC 1 9 2003

Living Data Technology Corporation
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

Re: K033657
Mobile External Counter Pulsation System AngioNew-V
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsating Device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: November 19, 2003
Received: November 21, 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.

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) 594-4646. 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.

Sincerely yours,

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

Enclosure

EXHIBIT B

510(k) Number (if known): K033657

Device Name: The Mobile External Counter Pulsation System AngioNew-V

Indications for Use:

The Mobile External Counter Pulsation System AngioNew-V is a non-invasive external counter pulsating device intended for use in the treatment of patients with congestive heart failure, stable or unstable angina pectoris, actual myocardial infraction or cardiogenic shock.

(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 K033657