K023701

EXHIBIT #1

JAN 3 0 2003

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:

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

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

Date Summary Prepared:

October 31, 2002

2. Name of the Device:

AngioNew-IV

3. Predicate Device Information:

1. Vasogenics, Inc., K#940264, Vasogenics EECP-MC2, Port Jefferson Station, NY.

2. Vasomedical, Inc., K020857, Enhanced External Counterpulsation EECP®MC-2 External Counter Pulsating Device, Westbury, NY.

3. Beit Hapa'amon Automatic External Counterpulsating Device (AECP-A), K# 012141, Kfar Saba, Israel.

4. Device Description:

The Mobile External Counter Pulsation System AngioNew-IV 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 Technologies AngioNew-IV 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 diatolic period, pressure is applied sequentially from calves to thighs and then to buttocks to force blood back to the hear, increase coronary perfusion pressure (diatolic and augmentation) and, at the same time, increases coronary blood flow and enchances 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 Just before the heart starts ejecting blood during systolic period, air is quickly withdrawn from all cuffs simultaneously to remove all the external applied pressure, leaving behind empty vasculature in the lower extremities to receive the output of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.

5. Intended Use:

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

6. Comparison to Predicate Devices:

All major components of LDT AngioNew-IV are same in function and specifications as the predicate device Vasogenics/Vasomedical EECP-MC2 System, with the exception of three components. They are: Inflation/deflation timing control, valves and the dimensions of cuffs. These differences do not result in any changes in the precautions or contraindications of the device, nor any changes in the intended use, safety and effectiveness of the device. See discussions below.

An additional difference between AngioNew-IV and EECP MC-2 is the use of artery plethysmography. AngioNew-IV uses the same temporal artery sensor as in the AECP-A, another predicate device.

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

In addition to electrical safety testing in accordance with IEC 60601-1, and EMC testing in accordance with IEC 60601-1-2, En 55011, EN 6100-4-2, EN 61000-4-3, EN 61000-4-4 and EN 61000-4-5, testing was also conducted:

Critical Functions:

- ECG Signal Processing
- QRS Detection and Inflation/Deflation Timing
- Effective Heart Rate Range
- Inflation/Deflation Duration Time
- Time Intervals between the Three Sequential Inflation Signals

Non-Critical Functions:

- CRT Display Freezing
- CRT Display Sweep Speed
- Treatment Timer
- Number Display on CRT

9. Conclusions:

The subject device, AngioNew-IV, has the same intended use and similar characteristics as the predicate devices. Morever, 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-IV device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 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: K023701
The Mobile External Counter Pulsation System AngioNew-IV
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsating Device
Regulatory Class: Class III (three)
Product Code: 74 DRN
Dated: October 31, 2002
Received: November 4, 2002

Dear Ms. Goldstein-Falk:

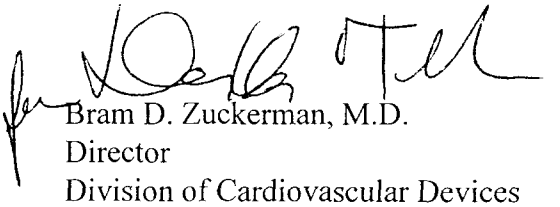
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

Exhibit B

510(k) Number (if known): K023701

Device Name The Mobile External Counter Pulsation System AngioNew-IV

Indications For Use:

The Mobile External Counter Pulsation System AngioNew-IV is a non-invasive external counter pulsation device intended for use in the treatment of patients with congestive heart failure, stable or unstable angina pectoris, acute myocardial infarction 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 K023701

Prescription Use Only