K042413

DEC - 9 2004

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APPLIED CARDIAC SYSTEMS INC.
NCP-2
510 (k) Summary

1. Date Prepared: 24 August 2004

2. Submitter's Name: and Address

Applied Cardiac Systems, Inc.
22912 El Pacifico Drive
Laguna Hills, CA 92653

3. Contact Person:

R. Ben Ghadimi
Senior Vice President of Regulatory Affairs
Applied Cardiac Systems, Inc.
Telephone: (949) 855-9366
Facsimile: (949) 581-1009
E-mail: bghadimi@ acs.occoxmail.com

4. **Device Name:** ACS Model NCP-2 External Counterpulsation Device

Proprietary Name: ACS Model NCP-2 External Counterpulsation Device

Common Name: External Counterpulsation Device (ECP)

Classification Name: Device, Counter-pulsating, External

5. **Predicate Device:** Nicore NCP (ESP) External Counterpulsation Device K980937 and by reference K023016 (adding Congestive heart failure to the indications for use of the device)

6. **Device Description:**

The ACS Model NCP-2 External Counterpulsation Device (ECP) is comprised of three major components, a *Control Console*, a *Treatment Bed*, and a set of patient *Cuffs*. The device is a microprocessor-controlled system that inflates and deflates three pairs of air cuffs, which compress vascular beds in the muscles of the calves, thighs, and buttocks to achieve the desired therapy.

The *Control Console* is comprised of a signal amplifier module, a power module, a microprocessor control module, a keyboard control panel with trackball, a Liquid Crystal Display (LCD) panel, and a Personal Computer (PC) with storage drives, data entry QERTY keyboard, network card, and printer. Control console input and data from the ECG, finger plethysmograph, and the pressure/vacuum transducers are processed by the microprocessor to control the valve timing and pressure delivered to the cuffs. Treatment pressure is monitored with an internal pressure sensor and the operator-selected set point maintained by a closed-loop control system. Valve inflation and deflation timing is also set by the operator based on the relative position of the R-wave of the patients ECG.

The PC is used to enter patient demographics, record pre and post-treatment data, and process data acquired by the microprocessor module to display user feedback for the ECP treatment on the LCD showing treatment parameters and patient waveforms during use.
An internal hard disk drive is used to store data on the system, a CD/DVD drive is used to record data onto removable media, and a printer is used to produce hard copy of a report that includes all of the pertinent treatment data for individual treatments and a session summary of all treatment data collected for 35 or more days.

The *Treatment Bed* accommodates the air compressor, a pressure and vacuum reservoir, inflation and deflation valves and a motorized lifting mechanism for the mattress assembly. The motorized lifting mechanism is used to move the mattress up and down, providing a convenient height for patient and operator use. The valve assembly consists of three pairs of inflation and deflation valves that open and close on command to inflate or deflate the patient *Cuffs* with air. The valve manifold assembly is connected to the air compressor and pressure/vacuum reservoir components via connecting air hoses. External pressure is delivered to the lower extremities of the patient in synchronization with the heart, i.e. the cuffs compress vascular beds in the calves, lower thighs and upper thighs/buttocks on inflation.

When the heart is in its relaxed state during the diastolic period, pressure is applied sequentially from the calves, to the lower thighs, to the upper thighs and buttocks, forcing blood back to the heart, increasing coronary perfusion pressure and coronary blood flow (diastolic augmentation), as well as venous return. Immediately before the heart begins to eject blood during the next systolic phase, the *Cuffs* are rapidly deflated and all externally applied pressure is eliminated. The vasculature in the lower extremities re-conforms and is able to receive the output of the heart with lessened resistance, thereby reducing systolic pressure and the workload of the heart (decreased after-load).

Stretchable treatment pants comprised of cotton and Lycra (Spandex) are worn by the patient under the Patient *Cuff* Set to allow for greater comfort during treatment.

7. **Intended Use**: ACS Model NCP-2 External Counterpulsation Device is a non-invasive external Counterpulsation device intended for the use in the treatment of patients with stable or unstable angina pectoris, acute myocardial infarction, cardiogenic shock or congestive heart failure.

8. **Comparison of Technological and functional characteristics** :

Characteristics of the ACS Model NCP-2 External Counterpulsation Device **are identical to** the predicate device; Nicore Model NCP (ESP) (K980937) and (K023016). Principles of operation are identical.

9. **Non-clinical Tests**: Non-clinical testing on the ACS Model NCP-2 External Counterpulsation Device included the following:

- **Software verification and validation, as follows**:

  - Functional requirements as defined in the NCP (ESP) System Requirements Specification.
  - Boundary values and stress testing as defined by FDA's Guidance for the Content of Premarket Submission for Medical Devices Containing Software, CDRH, ODE, FDA, May, 1998.
  - Safety requirements as identified safety risk analysis performed in accordance with EN 1497 1 – 1 Medical Device Risk Analysis, October, 1994, the "Essential Requirements of the Medical Devices Directives", 14 June, 1993, and IEC 601-1-4, Medical Electrical Equipment Part 1 : General requirements for safety. 4 Collateral Standard: Programmable electrical medical systems, 1996-05.
  - Testing in support of validation in accordance with the FDA's General Principles of Software Validation, Final Guidance for Industry and FDA Staff, January 11,2002, and **IEC** 601-1-4, Medical Electrical Equipment Part 1: General requirements for safety, 4 Collateral Standard: Programmable electrical medical systems, 1996-05.

- **Verification of System operation, as follows:**

  - Functional requirements as defined in the NCP (ESP) System Requirements Specification to verify the performance of the device at the system level.
  - Safety requirements as identified in the safety risk analysis performed in accordance with EN 1497 1 - 1, Medical Device Risk Analysis
  - Additional verification tests, as indicated, to verify performance at the component level recognized standards IS0 10993-1, IS0 10993-5, IS010993-10 and IS0 10993-12.

10. **Clinical Evaluation**:

An Independent Review Board has overseen the clinical investigation of the External Counterpulsation Device. Results have demonstrated substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Applied Cardiac Systems, Inc.
c/o Mr. R. Ben Ghadimi
Senior Vice President of Regulatory Affairs
22912 El Pacifico Drive
Laguna Hills, CA 92653

Re: K042413
ACS™ Model NCP-2
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsating Device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: November 22, 2004
Received: November 26, 2004

Dear Mr. Ghadimi:

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,

Donna R. Lachman

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

Enclosure

Indications for Use

510(k) Number (if known): K042413

Device Name: Device, Counterpulsating, External

Indications For Use:

Current indications for use of the ACS™ Model NCP-2 are:

- Stable Angina Pectoris
- Unstable Angina Pectoris
- Acute Myocardial Infarction
- Cardiogenic Shock
- Congestive Heart Failure

Predicate Indication for Use

Taken from Predicate literature (*See also, Predicate Labeling, Section C*)

"The Nicore™ Model NCP (ESP) External Counterpulsation System is a non-invasive external counter pulsation device for the treatment of patients suffering from stable or unstable angina pectoris, acute myocardial infarction, cardiogenic shock, and congestive heart failure."

Prescription Use _Yes_ AND/OR Over-The-Counter Use _____
(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)

Donna R Vochniak

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on of Cardiovascular Devices

) Number K042413