1C030532

(510k) Summary

CPCA2000, Inc.
CPCA2000 Counterpulsation System

MAR 1 4 2003

1. Date Prepared:

2. Submitter's Name and Address:

CPCA2000, Inc.
6336 17Th Street Circle East
Sarasota, FL 34243

3. Contact Person:

Rod Shipman, President
CPCA2000, Inc.
Telephone (941) 727-4370
Facsimile: (941) 727-4371

4. Device Name:

CPCA2000™ Counterpulsation System

Proprietary Name:

CPCA2000™ Counterpulsation System

Classification Name:

Device, Counter-pulsating, External

5. Predicate Device:

The CPCA2000™ Counterpulsation System is substantially equivalent to the Enhanced External Counterpulsation Device - Model EECP-MC2. FDA granted 510(k) clearance for the predicate device on February 23, 1995 (K940264).

6. Device Description:

The CPCA2000 Counter Pulsation System consists of a portable console containing computer, electrocardiogram, plethysmogram, pump and reservoir, integral strip chart recorder, and leg cuffs and hoses. The microprocessor is used to operate and monitor the system via proprietary software, with the operator using touch screen interface to control its operation. The screen displays information pertinent to operating the system, as well as treatment parameters and patient waveforms during use. An external floppy disk drive is used to record data onto transferable media, and a printer is used to produce a hard copy of site, patient and physiologic data. The system accommodates the use of any bed or treatment table.

External pressure is applied via the patient cuff set 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 though/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 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 reconforms and is able to receive the output of the heart with lessened resistance, thereby reducing systolic pressure and the workload of the heart (decreased afterload).

7. Intended Use:

The CPCA2000™ Counterpulsation System is a non-invasive external counterpulsation device intended for use in the treatment of patients with stable or unstable angina pectoris, congestive heart failure, acute myocardial infarction and cardiogenic shock. Use of this device may reduce pain and impairment associated with angina pectoris, congestive heart failure or myocardial infarction and may enhance coronary function.

8. Comparison of Technological Characteristics:

The principle technological and functional characteristics of the current device are same as the predicate devices. The treatment of congestive heart failure patients with the CPCA2000 ECP system does not require any changes in software, device design or treatment regimen. The treatment of this patient population does not significantly change the safety and effectiveness of the device.

9. Non-Clinical Tests:

Key non-clinical testing conducted on the CPCA2000™ Counterpulsation System includes the following:

- IEC60601-1-2; 2001 Medical Electrical Equip., Part 1-2, General Requirements for Safety; Collateral Standard, Electromagnetic Compatibility
- UL 2601-1 Medical Electrical Equipment, Part1: General Requirements for Safety
- Software Verification & Validation, per Guidance for the Content of Premarket Submission for Medical Devices Containing Software, CDRH, ODE, FDA, May, 1998.
- Device Risk & Hazard Analysis per 21CFR820.30(g), Design Validation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2003

CPCA2000, Inc.
c/o Mr. Michael P. Dayton
BioMed Research, Inc.
4608 Rue Bordeaux
Lutz, FL 33558

Re: K030532
Trade Name: CPCA2000™ Counterpulsation System
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsating Device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: February 14, 2003
Received: February 19, 2003

Dear Mr. Dayton:

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

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510k Number (if known): K030532

Device Name: CPCA2000™ Counterpulsation System

Indications For Use:

The CPCA2000™ Counterpulsation System is a non-invasive external counterpulsation device intended for use in the treatment of patients with stable or unstable angina pectoris, congestive heart failure, acute myocardial infarction and cardiogenic shock. Use of this device may reduce pain and impairment associated with angina pectoris, congestive heart failure or myocardial infarction and may enhance coronary function.

(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 [illegible]

510(k) Number K030532

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-