K023016

NICORE™

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DEC 0 4 2002

Premarket Notification [510(k)] Summary

1. Submitted by: NICORE, Inc.
4897 W. Waters Ave., Suite J
Tampa, FL 33634

Telephone: (813) 901-0019 Fax: (813) 901-0415

2. Contact person: Jeff Mogilewicz
Quality Assurance Manager

3. Name of the Device

a. Trade Name: NICORE Model NCP-1 External Counterpulsation Device

b. Common Name: External Counterpulsation Device (ECP)

c. Classification Name: Counter-pulsating device, external

4. Legally Marketed Device for Which We are Claiming Substantial Equivalence:

Vasomedical Model EECP-MC2

5. Description of the Device:

The NICORE Model NCP-1 is a proprietary, non-invasive medical device for performing external, sequential counterpulsation. It 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.

6. Intended use of the Device:

Current Indications for use includes treatment of patients with:

- Stable and unstable angina pectoris
- Acute myocardial infarction
- Cardiogenic shock
- Congestive Heart Failure

7. Summary Comparison of Technological Characteristics to Predicate Device

Technological characteristics of this device which are similar to those of the predicate include: The number of major components (four); the triggering mechanism (patient's ECG R-wave); manual controls; non-PC based; emergency system power down; external strip chart recorder; circuit boards; maximum pressure used for treatment.

Technological characteristics of this device which are different than the predicate include: Through-hole circuit board versus a handwired/soldered board; patient's call button; operator's console displays more data simultaneously; pressure cuffs are vacuum deflated; treatment surface is contoured for safety and comfort; safety interlock requiring external ECG signal before treatment can start; air pump and air supply hoses are housed within the treatment table.

8. Discussion of Clinical Tests

Prior to marketing approval of the NCP-1 a clinical study was completed to compare the NCP-1 device with the predicate. The study used nine healthy volunteers, average age 44 (range 29-59). Following screening, the subjects were randomly assigned to each device in an alternating manner and the sequential readings were taken at treatment pressures of 0.15 KPa, 0.20, 0.25, 0.30, 0.35, and 0.40 KPa. After a 90-minute rest, the subjects underwent final treatment on the other brand of the device.

Data collected included the degree of diastolic augmentation. This was measured as a ratio of peak diastolic to peak systolic pressure, as determined by measurement and calculation of the amplitude and area of the representation of the patient's pulse pressure wave. The mean for the amplitude ratio on the NICORE device was 1.50, as compared to the Vasomedical device of 1.51. The mean for the area ratio on the NICORE device was 1.84 and on the Vasomedical device was 1.82. The means for the two ratios are within one standard deviation of the overall mean of the combined data. The combined amplitude ratio overall mean for both devices was 1.50 at one standard deviation of 0.62; for the area relation for both devices, the combined overall mean was 1.83, at one standard deviation of 0.82

9. Summary of Conclusions Drawn from Clinical Tests

Based on the testing performed on the test subjects, data analysis of the results indicates that the two sets of data obtained from the NICORE and Vasomedical devices belong to the same population and are therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2002

NICORE, Inc.
c/o Mr. Jeff Mogilewicz
Quality Assurance Manager
4897 W. Waters Avenue, Suite J
Tampa, FL 33634

Re: K023016
Trade Name: NICORE Model NCP-1 External Counterpulsation Device
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counterpulsation Device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: September 6, 2002
Received: September 10, 2002

Dear Mr. Mogilewicz:

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). 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

510(k) Number (if known): K023016

Device Name: NICORE Model NCP-1 External Counterpulsation Device

Indications For Use: The NICORE Model NCP-1 is used to provide external counterpulsation (ECP) therapy, and is indicated for use in the treatment of stable or unstable angina pectoris, congestive heart failure, cardiogenic shock, and acute myocardial infarction.

(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
and Respiratory Devices

510(k) Number K023016

(Optional Format 3-10-98)

X Prescription Use