510(k) Summary

JUN 1 4 2002

Vasomedical, Inc.
EECP® Therapy System Model TS3 with Pulse Oximetry

1. Date Prepared: 13 June 2002

2. Submitter's Name: and Address
Vasomedical, Inc.
180 Linden Ave.
Westbury, NY 11590

3. Contact Person:
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Vasomedical, Inc.
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4. Device Name:
Vasomedical, Inc.
EECP® Therapy System Model TS3 with Pulse Oximetry
EECP® Therapy System Model TS3
Enhanced External Counterpulsation EECP® MC-2

Proprietary Name:
EECP® Therapy System Model TS3 with Pulse Oximetry
EECP® Therapy System Model TS3
Enhanced External Counterpulsation EECP® MC-2

Common Name:
Enhanced External Counterpulsation (EECP®) Therapy System

Classification Name:
Device, Counter-pulsating, External

5. Predicate Device:
The EECP® Therapy System Model TS3 with Pulse Oximetry is substantially equivalent to the EECP® Therapy System Model TS3 (K003469) and, by reference, to the EECP® MC-2 (K940264).

6. Device Description:
The EECP® Therapy System Model TS3 with Pulse Oximetry is comprised of three major components, a Control Console, a Treatment Table, and a patient Cuff Set.

The Control Console accommodates the air compressor and reservoir, a signal module panel, a power module, a microprocessor with touch screen/keyboard interface, data storage drives and printer, and components for acquiring and processing ECG, finger plethysmograph and oxygen saturation signals. The microprocessor is used to operate and monitor the system by means of proprietary custom software, with the operator using the touch screen/keyboard interface to control its operation. The screen displays information pertinent to operating the system, as well as treatment parameters and patient waveforms during use. Treatment pressure is monitored with an internal pressure sensor and the operator-selected set-point maintained by a closed-loop control system. The touch screen employs "hardware-less keys" which the operator touches to select a function or execute a command and the keyboard enables alphanumeric text entries. An internal hard disk drive is used to store data on the system, an internal floppy disk drive is used to record data onto transferable media, and a printer is used to produce hard copy of site and patient identifiers and physiologic data.

The Treatment Table accommodates a motorized lifting mechanism, mattress and the pneumatic circuit valve 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/deflation valves that open and close on command to inflate or deflate the patient Cuff Set with air. The valve assembly is connected to the air compressor and reservoir components in the Control Console via connecting air hoses.

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 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

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). 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.

The Model TS3 with Pulse Oximetry incorporates a non-invasive sensor and electronic module to acquire and process the patient's oxygen saturation. These same components functions can be used separately or simultaneously. The Nonin oxygen saturation metering device has been an added feature to the following devices:
- NONIN® Pulse Oximeter and Carbon Dioxide Detector (K982969)
- 9303 Neonatal/Adult Vital Signs Monitor (K982776)
- MTS Option for the ESCORT® II Monitor (K970763)
- Nonin® PalmSAT®, Model 2500, Pulse Oximeter with 2500C & 2500B (K002690)

Key differences between the current device and the modified device include:

- Congestive heart failure has been added to the indications for use of the device.
- Contraindications for left ventricular hypertrophy and cardiomyopathy have been removed from the device's labeling.
- A pulse oximetry function has been added to measure and display oxygen saturation in adult patients in a professional setting.
- The display has been modified to allow the operator to simultaneously display ECG, inflation/deflation time, finger plethysmography, heart rate, ratio of pressure amplitudes, ratio of area under pressure waveform, treatment time and functional oxygen saturation.
- Modifications to the Pressure Control components to enable the operator to set the desired treatment pressure with less presses of up/down touch keys, automatic maintenance of the treatment pressure set point, and holding of the treatment pressure set point when the system is placed in "Standby" mode.

7. Intended Use: The EECP® Therapy System Model TS3 with Pulse Oximetry is a non-invasive external counterpulsation device intended for the use in the treatment of patients with congestive heart failure, stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.

8. Comparison of Technological and functional characteristics of the

Technological Characteristics: modified device are essentially the same as those of the predicate device. Principles of operation are the same.

9. Non-clinical Tests: Non-clinical testing on the EECP® Therapy System Model TS3 with Pulse Oximetry included the following:

- Software verification and validation, as follows:
  - functional requirements as defined in the EECP® Therapy System Model TS3 with Pulse Oximetry 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 in the safety risk analysis performed in accordance with EN 14971-1, 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 EECP® Therapy System Model TS3 with Pulse Oximetry System Requirements Specification to verify the performance of the modified device at the system level.
  - safety requirements as identified in the safety risk analysis performed in accordance with EN 14971-1, Medical Device Risk Analysis.
  - additional verification tests, as indicated, to verify performance at the component level.
  - biocompatibility testing in conformity with recognized standards ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-12.

10. Clinical Evaluation:

Clinical evaluation of EECP® in patients with congestive heart failure has been performed in multi-center, single center and registry-based clinical investigations. Results of these investigations have demonstrated clinical benefit in patients treated with Vasomedical EECP® Therapy Systems. Objective measures such as peak oxygen consumption, exercise duration and pre-load adjusted maximal left ventricular power are improved following EECP® therapy, as well as subjective measures of patient response to therapy, such as quality of life and functional ability measures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2002

Vasomedical, Inc.
c/o Mr. Thomas R. Varricchione, MBA, RRT
Vice President, Clinical Research and Regulatory Affairs
180 Linden Avenue
Wesbury, NY 11590

Re: K020857
Trade Name: EECP® Therapy System Model TS3, Model TS3 with Pulse Oximetry , and Enhanced External Counterpulsation EECP® MC-2 External Counter-pulsating Devices
Regulation Number: 21 CFR 870.5225
Regulation Name: Device, Counter-pulsating, External
Regulatory Class: Class III (three)
Product Code: DRN
Dated: March 15, 2002
Received: March 18, 2002

Dear Mr. Varricchione:

This letter corrects our substantially equivalent letter of June 14, 2002, regarding the trade names referenced in your submission.

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). 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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indication for Use Statement

510(k) Number: K020857

Device Name: EECP® Therapy System Model TS3 with Pulse Oximetry
External Counter-pulsating Device

Indications for Use: Vasomedical, Inc.'s EECP® Therapy System Model TS3 with Pulse Oximetry is a non-invasive external counterpulsation 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)

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

Division of Cardiovascular & Respiratory Devices
510(k) Number K020857

Indication for Use Statement

510(k) Number: K020857

Device Name: EECP® Therapy System Model TS3
External Counter-pulsating Device

Indications for Use: Vasomedical, Inc.'s EECP® Therapy System Model TS3 is a non-invasive external counterpulsation device intended for use in the treatment of patients with congestive heart failure, stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.

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(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020857

Indication for Use Statement

510(k) Number: K020857

Device Name: Enhanced External Counterpulsation EECP® MC-2
External Counter-pulsating Device

Indications for Use: Vasomedical, Inc.'s Enhanced External Counterpulsation EECP® MC-2 is a non-invasive external counterpulsation device intended for use in the treatment of patients with congestive heart failure, stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Per 21 CFR 801.109)

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