K052611

APR 2 6 2006

Attachment

510(k) Summary

ECP Health, Inc.
ECP Health System Model 2005

1. Date Prepared:	August 22, 2005
2. Submitter's Name: and Address	ECP Health, Inc. 8416 Prairie Rose Lane Fort Worth, TX 76123
3. Contact Person:	Shamon Huang, M.S. Vice President ECP Health, Inc. Tel: (817)253-2891 Fax: (817)292-8265
4. Device Name: Proprietary Name: Common Name: Classification Name:	ECP Health System Model 2005 ECP Health System Model 2005 External Counterpulsation Device Device, Counter-pulsating, External
5. Predicate Device:	The ECP Health System Model 2005 is substantially equivalent to S-TCT Health External Counterpulsation Device (FDA granted 510(k) clearance on May 30, 2003 -- K030587)
6. Device Description:	ECP Health System Model 2005 is a positive and negative pressure integrated , non-invasive medical device for performing external sequential counterpulsation. It is a microprocessor-controlled system that inflates and deflates three parts of air cuffs which compress vascular beds in the calves, lower thighs, and upper thighs /buttocks to achieve the desired therapy.
7. Intended use:	The intended use of the ECP Health System Model 2005 is for the treatment of patients with:

(1). Stable or unstable angina pectoris.
(2). Acute myocardial infarction
(3). Cardiogenic shock
(4). Congestive heart failure

8. Key difference between the current device and the predicate device:

(1): Congestive heart failure has been added to the indications for use of the device
(2): Unstable angina pectoris has been added to the indications for use of the device
(3): A finger pulse oximetry function has been added to measure and display oxygen saturation.

9. Comparison of Technological Characteristics :

Technological and functional characteristics of the ECP Health System Model 2005 are essentially the same as those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2006

ECP Health Inc.
c/o Mr. Shamon Huang
Vice President
8416 Prairie Rose Lane
Fort Worth, TX 76123

Re: K052611
ECP Health System Model 2005
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsation Device
Regulatory Class: Class III
Product Code: DRN
Dated: March 10, 2006
Received: March 17, 2006

Dear Mr. Huang:

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 (240) 276-0120. 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 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): K052611

Device Name: **ECP Health System Model 2005**

Indications for Use:

The intended use of the ECP Health System Model 2005 is for the treatment of patients with:

(1). Stable or unstable angina pectoris.
(2). Acute myocardial infarction
(3). Cardiogenic shock
(4). Congestive heart failure

Prescription Use _yes_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052611