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510(K) SUMMARY

(SPECIAL CONSIDERATION)

MAY 29 2008

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is K081359.

Date: April 18, 2008

Submitted by: ScottCare Corporation
Registration No: 1527715
4791 West 150th Street
Cleveland, OH 44135

Contact Person: Mr. Ronald J. Clines
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216-264-6129 Fax
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Manufacturing Site: ScottCare Corporation
Registration No: 1063268
4897 W. Waters Ave, Suite J
Tampa, Florida 33634

Trade Name: ScottCare Genesis ECP Device

Common Name: External Counter Pulsation (ECP) device

Classification: 870.5225
External counter-pulsating device,

Product Code: DRN

Legally Marketed Predicate Device(s):
Model NCP-1 Counter Pulsation Device
K023016, December 12, 2002

2-0001

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Device Description:

The "Genesis" is a 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. The microprocessor's primary function is to serve as an R-wave detector, calculate the R-wave rate (heart rate), and deliver triggering signals to actuate valves that allow the cuffs to be filled during the diastolic period and then emptied prior to systole. The secondary function of the microprocessor is to output, through a serial port, information necessary for displaying patient treatment data on a video monitor. This data allows a trained operator to fine-tune the inflation/deflation signals to optimize a patient's diastolic augmentation.
The cuffs are snugly wrapped around the patient's calves, thighs, and buttocks to allow compression of vascular beds in these body areas. To prevent skin irritation the patient is typically dressed in tight fitting, stretchable treatment pants prior to being fitted with the cuffs. As diastole begins, the cuffs inflate sequentially proceeding from the calves, to the thighs, to the buttocks, with the inflation sequence taking a total of approximately 200ms. The inflation sequence generates and drives an arterial counter pulsation wave creating an increase in coronary perfusion pressure and coronary blood flow. The compression sequence also increases venous return, which increases stroke volume and cardiac output. At the end of diastole, and just before the next QRS complex, the cuffs are evacuated simultaneously over a period of approximately 120ms. The course of treatment is typically 35 1-hour treatments administered 5 days a week. The device automatically stops compression of the cuffs and releases all pressure in the cuffs upon completion of the pre-set treatment timer.

The system consists of two major assemblies: 1) the patient bed that houses the electronic pneumatic controls / valves, compressor / vacuum pump and associated power supplies and 2) the operator's console that consists of an all-in-one computer/monitor, computer peripherals (keyboard and pointing device) and a control panel.

Indications for Use:

The ScottCare Genesis ECP is a non-invasive external counterpulsation (ECP) device indicated for use in the treatment of stable or unstable angina pectoris, congestive heart failure, cardiogenic shock and acute myocardial infarction.

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Substantial Equivalence:

Features	The Modified Genesis Model	Predicate Device NCP-1
510(k) Number	TBD	K023016
Date Cleared	TBD	12/12/2002
Intended Use	The intended use of the ScottCare Genesis device is 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.	The intended use of the NCP-1 device is 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.
Bed Enclosure	Aluminum panels / welded	Furniture grade compressed wood / fasteners & glue
Pump	Integral compressor / vacuum 220VAC 15A 60Hz (UL listed) 50Hz Option (UL Listed)	Integral compressor / vacuum 120VAC, 30A, 60Hz
nflate / Deflate Valve	6 per bed, Voltage controlled 24VDC	6 per bed, Voltage controlled 24VDC
Emergency relief valve	3 per bed, Normally open, voltage controlled 24VDC	3 per bed, Normally open, voltage controlled 110VAC
Vacuum Tank Relief Valve	1 per bed, Voltage controlled 24VDC	1 per bed, Voltage controlled 24VDC
Air Valve Type	Magnetic bobbin, Normally Closed, spring	Magnetic bobbin, Normally Closed, spring
Pressure Tank Relief	Mechanical Type Calibrated at 8PSI	Mechanical Type Calibrated at 8PSI
Power Supply	(2) Switching Medical Grade Located in bed base	(2) Step down transformer Located in the Operator's Console cabinet
Bed Function Control	Xilog Z-80 CPU integrated on motherboard	Xilog Z-80 CPU integrated on motherboard
Data Display Device	Flat Panel LCD Computer Display	CRT Display
Panel Control Type	Membrane style, momentary, panel type	Non-sealed, latching pushbutton, panel type
Operator's Console	Floor standing pole type W/casters	Metal enclosure, floor type W/casters

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As the above chart demonstrates, the Genesis model ECP bed is substantially equivalent to the NCP-1 ECP bed that was cleared on December 12, 2002. Basic control functions remain unchanged and there are no significant technological changes to the device. The changes are predominantly cosmetic in nature and include:

- Changing from a CRT display screen to a flat panel LCD computer type display.
- Elimination of the large roll-around control console (that housed the CRT display) and utilize a pole style, roll around to mount the all-in-one computer /LCD display and control panel.
- Changing the construction of the bed base from compressed wood to aluminum and present a smaller overall footprint.
- Changing the control panel switches from latching, push-button style to a momentary, membrane style. To support this change a minor software (firmware) change was required.
- Provision for 50Hz operation where required.
- Simplification of the internal power supply to use switching, medical grade power supplies instead of discrete step down / rectification.
- Emergency relief valves (normally open) were changed to operate at 24V DC instead of at 120V AC. The control mechanism, construction and overall action of the valves remain unchanged. Lower voltage valve standardizes the control voltage within the device to a safer, 24V DC level.

The intended use of the modified device, as described in its labeling, has not changed as a result of these modifications. No technologically significant changes have occurred.

Conclusion:

Appropriate testing was conducted in accordance with established design control procedures. Testing demonstrated that the device functioned as designed and that the device was in compliance with IEC60601 Medical Device Safety and EMC testing requirements. The modified device, which is to be marketed as the "ScottCare Genesis" ECP Treatment device, is substantially equivalent to the predicate device.

2-0004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2008

ScottCare Corporation
Ronald J. Clines
Manager Regulatory/Quality
4791 West 150th Street
Cleveland, OH 44135

Re: K081359
Trade/Device Name: ScottCare Genesis External Counter Pulsation (ECP) Device
Regulation Number: 21 CFR 870.5225
Regulation Name: External counter-pulsation device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: April 30, 2008
Received: May 15, 2008

Dear Mr. Clines:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

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): K081359

Device Name: ScottCare Genesis External Counterpulsation Device

Indications for Use:

The intended use of the ScottCare Genesis ECP device is 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.

Prescription Use ✓ 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)

2-0005

Donna R. Bachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081359