K073038

510(k) Summary of Safety and Effectiveness

Carematix™ Wellness System

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

Submitter

Carematix™, Inc.
120 S. Riverside Plaza, Suite 2100
Chicago, IL 60606

Contact Person

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JAN 11 2008

Date Prepared:

October 23, 2007

Name of Device

Carematix™ Wellness System

Classification Names

Radiofrequency Physiological Signal Transmitters and Receivers

Device Classification

Regulatory Class:	Class II
Product Code:	DRG
Classification Panel:	Cardiovascular Device Panel
Regulation Number:	21 CFR 870.2910

Predicate Devices

K040966	Carematix™ Wellness System	Carematix™, Inc.

Description of Device

The Carematix™ Wellness System is intended to gather and transmit patient data from the home site or remote location to caregivers at a clinical facility where it provides supplemental information for the care of the patient.

The **Carematix™ Wellness System** consists of wireless radiofrequency transmitter adapters, a communication hub or receiving station, and an internet server:

- The radiofrequency transmitter adapter is connected, either wired directly or to a serial port, of monitoring devices currently in distribution having capability to monitor patient parameters for blood pressure, pulse rate, blood sugar, blood oxygen saturation, PT/INR, and FEVR/PEF.
- The communications hub, or receiving station, collects and stores data transmitted from each of the radiofrequency transmitter adapters and transmits patient data to the internet server at specified intervals.

- The internet server receives the patient data from the home setting or remote location where it is made available to the caregiver to track, graph, trend, note

- variances, set alert criteria, and receive alerts when parameters are outside the criteria set.

Indications For Use
The Carematix™ Wellness System is a physiological monitoring system. The system collects, accumulates and transmits patient vital signs and other physiological data from a patient who may be remote from the healthcare practitioner to the practitioner. It is intended for patient home use for the following and can record physiological information such as:

Non-invasive blood pressure measurement;
Pulse rate measurement;
Blood glucose level using a Glucometer;
Blood hemoglobin oxygen saturation (%SpO_2) using a digital Pulse Oximeter;
Prothrombin Time (PT) and International Normalized Ratio (INR) measurement using an in-home coagulation measurement system;
Peak Expiratory Flow Rate (PEFR) and Forced Expiratory Volume (FEV) measurements using an electronic peak flow meter;
Patient weight using a stand-on electronic scale

The results of these measurements are transmitted to a computer monitoring station in a clinical setting via common telephone lines from the patient's home setting.

Nonclinical Performance
The Carematix™ Wellness System was tested and passed all required electrical and mechanical testing.

Clinical Performance
The Carematix™ Wellness System performance was tested with clinical data and the results met the acceptable criteria.

Conclusion
The Carematix™ Wellness System is substantially equivalent to the following 510(k) cleared devices:

Carematix™ Wellness System cleared under K040966 on June 2, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

Carematix Inc.
c/o Sukhwant Khanuja, Ph.D.
Chief Executive Officer
120 S. Riverside Plaza, Suite 2100
Chicago, IL 60606

Re: K073038
Trade/Device Name: Carematix™ Wellness System Model CWS-5000.1-B
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: December 11, 2007
Received: December 13, 2007

Dear Dr. Khanuja:

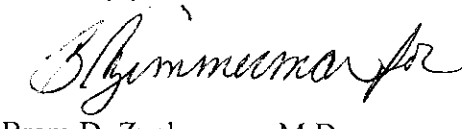
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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 K073038

Device Name: Carematix™ Wellness System

Indications for Use:
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The results of these measurements are transmitted to a computer monitoring station in a clinical setting via common telephone lines from the patient's home setting.

Prescription Use ___X___ and/or Over-the-counter Use _____
(per 21 CFR 801.109)

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 Devices
510(k) Number K073038