510(k) Summary

Carematix™ Wellness System

MAY - 5 2010

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.
209 W Jackson Blvd, Suite 800
Chicago, IL 60606

CONTACT PERSON

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Date Prepared:

February 15, 2010

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; K073038- 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 FEV/PEFR.
- The communications hub, or receiving station, collects and stores data transmitted from each of the radiofrequency transmitter adapters or wired device and transmits patient data to the internet server via PSTN, LAN, cellular, wireless etc.
- 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, note

variances, set alert criteria, and receive notifications 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.

PERFORMANCE TESTING

Verification and Validation tests were conducted for the Carematix Wellness System in accordance with Good Manufacturing Practices and the results met acceptable criteria. The Carematix™ Wellness System also conforms to requirements of IEC 60601-1 and we consider it safe and

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, and
Carematix™ Wellness System cleared under K073038 on Jan 11, 2008.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Carematix, Inc
c/o Sukhwant Khanuja, PhD
CEO
209 W Jackson Blvd, Suite 800
Chicago, IL 60606

MAY - 5 2010

Re: K100508
Trade/Device Name: Carematix Wellness System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: April 1, 2010
Received: April 5, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for 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 K100508

Device Name: Carematix™ Wellness System

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:

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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 K100508