K040966

JUN - 2 2004

EXHIBIT 2 - 510(k) Summary of Safety and Effectiveness

Carematix, Inc.
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April 05, 2004

Contact: Dr. Sukhwant Khanuja, Director

1. **Identification of the Device:**
   Proprietary-Trade Name: Carematix Wellness System
   Classification Names: DXN: System, Measurement, Blood-Pressure, Non-Invasive
   DRG: Transmitters And Receivers, Physiological Signal, Radiofrequency
   Common/Usual Name: Telemedicine system

2. **Equivalent legally marketed devices:** This product is similar in function to the M3810a Philips Telemonitoring System, **K023749** and Hewlett Packard Company Model 3810A, **K993169**; AvidCare Series 100 Telemanagement System, **K011779**; AvidCare Corporation Home Health Monitoring System, **K010029**; Viterion 100 Telehealth Monitor, **K030419**; Carematix Wellness System, **K031840**. The Carematix Wellness System only uses sensor devices already cleared with 510(k) approvals; OR provides adaptors for biometric measurement devices having existing 510(k) approvals. The Stand-on patient scale is exempt from pre-market notification as per 880.2700. Please refer to *Exhibit 4: System Description* for specific details on the sensor devices used with the Carematix Wellness Systems.

3. **Indications for Use (intended 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 (%SpO2) and pulse rate using a digital Pulse Oximeter; Prothrombin Time (PT) and International Normalized Ratio

(INR) measurement using an in-home coagulation measurement system; Body temperature measurement using a digital thermometry device or 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.

4. **Prescription Device:** Federal law (US) restricts this device to sale by or on the order of a physician.

5. **Description of the Device:** The Carematix Wellness System (CWS) provides easy monitoring of the basic wellness parameters via a wireless connection between the monitoring device and a hub (receiving station) located in the home. The hub transmits the information to the Carematix Internet server where the data is added to the patient's chart. Using a web-browser, the caregiver can track the patient's data, graph the results, monitor trends, annotate variances, set alert criteria, and send reminders and receive alerts via e-mail or pager. The following monitoring devices are currently available from Carematix: Blood pressure unit (Arm cuff and Wrist cuff), Weight Scale, Blood Glucose Meter adaptors, Pulse Oximeter adaptors, Coagulation Measurement System adaptors, Digital Thermometer adaptors, Peak Flow Meter adaptors.

6. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicate that the new device is as safe and effective as the predicate devices.
7. **Substantial Equivalence Chart**

Feature	Avid Care K011779 and K010029	Philips K023749	Viterion K030419	Carematix K031840	Carematix Modified System
Indications of Use	Enables healthcare providers to manage chronic conditions of patients remotely	Same	Same	Same	Same
Intended use	Telemedicine System	Same	Same	Same	Same
Intended Users	Home users and Health care provider	Same	Same	Same	Same
Site of Use	Home; clinic	Same	Same	Same	Same
Data	Avid Care	Philips	Viterion	Carematix	Carematix

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Collection Software	Proprietary software	Proprietary Software	Proprietary software	Proprietary software	Proprietary software
Data Collection Software Functionality	Transmit data from Sensor devices to Central database	Transmit data from Sensor devices to Central database	Transmit data from Sensor devices to Central database	Transmit data from Sensor devices to Central database	Transmit data from Sensor devices to Central database
Communication method of hub with central server	Via modem over telephone line	Same	Same	Same	Same
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	• Blood Pressure • Weight • Glucose levels • Oxygen Saturation • PT/INR • FEV/PEF	• Blood Pressure • Weight • Glucose levels • ECG	• Blood Pressure • Weight • Glucose levels • Oxygen Saturation • Temperature • FEV/PEF	• Blood Pressure • Weight • Glucose levels	• Blood Pressure • Weight • Glucose levels • Oxygen Saturation • PT/INR • Temperature • FEV/PEF
Implementation-method of collecting data from sensors	Modify off-the shelf sensors with previous 510(k) clearance by adding communications interface. Basic sensors unchanged.	Same	Same	Same	Same
Sensor Software	Sensor software unchanged	Sensor software unchanged	Sensor software unchanged	Sensor software unchanged	Sensor software unchanged
Connectivity	Wired to hub	Wired or Wireless to hub	Wired to hub	Wireless to hub	Wireless to hub
Communication method of hub with devices	Wired – over serial port	Wireless RF protocol	Wired – over serial port	Wireless RF protocol	Wireless RF protocol
Communications protocol	Serial protocol	Proprietary protocol	Serial protocol	Proprietary protocol	Proprietary protocol
Communication frequency	Wired	915MHz FCC assigned channel	Wired	915 MHz FCC assigned channel	915 MHz FCC assigned channel
Power Source	Wall power plug for hub (120 VAC/50-60~) and batteries in devices	Same	Same	Same	Same
Display	On devices and hub, and monitors connected to central server	On devices and hub, and monitors connected to central server	On devices and hub, and monitors connected to central server	On devices, and monitors connected to central server	On devices, and monitors connected to central server

8. Non-clinical Testing

Similar to the predicate device Viterion 100 (K030419) which further refers to Panasonic Telehomecare system (K004050), the Carematix Wellness System utilizes patient sensors that have already received 510(k) clearance. The testing to demonstrate substantial equivalence for this product similarly to the predicates relies on:

- Testing to meet the product requirements and functional specifications
- Verification that the physiologic data received by the patient monitors are stored properly; and
- Verification that the data is transmitted to the healthcare practitioner in a manner that maintains the security and integrity of the data.

9. Conclusion

After analyzing bench, electrical safety, FCC, and user testing data, it is the conclusion of Carematix, Inc. that the Carematix Wellness System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices. The modification to the Carematix Wellness System approved under K031840 submitted for approval in this application does not alter the fundamental scientific technology of the sensor devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Carematix, Inc.
c/o Sukhwant Khanuja, Ph. D.
CEO
2 N Lasalle St., Suite 1805
Chicago, IL 60602

Re: K040966
Trade Name: Carematix Wellness System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: April 12, 2004
Received: April 14, 2004

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 Office of Compliance at (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

Neil R.P. Ogden for

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

Enclosure

j) Indications for Use

510(k) Number K040966

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:

- Non-invasive blood pressure measurement;
- Blood glucose level using a Glucometer;
- Patient weight using a stand-on electronic scale
- Pulse rate measurement;
- 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;
- Body temperature measurement using a digital thermometer;
- Peak Expiratory Flow Rate (PEFR) and Forced Expiratory Volume (FEV) measurements using an electronic peak flow meter;

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 Device.

Federal law (US) restricts this device to sale by or on the order of a physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. O'Hara for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040966

Prescription Use X OR Over the Counter Use_____

(Per 21 CFR 801.109)