K031840
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EXHIBIT 2

510(k) Summary of Safety and Effectiveness

Carematix, Inc.
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Chicago, IL 60602
Ph: 312-332-2444
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June 13, 2003

Contact: Mr. 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. The Carematix Wellness System only uses sensor devices already cleared with 510(k) clearance; OR provides external adaptors for Blood glucose monitors having existing 510(k) clearances. The Stand-on patient scale is exempt from pre-market notification as per 880.2700.
3. **Indications for Use (intended use):** The Carematix Wellness System is intended for patient home use for the following:
   Non-invasive blood pressure measurement; measurement of blood glucose, 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. Prescription Device. Federal law (US) restricts this device to sale by or on the order of a physician.

4. **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.

5. **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.

6. Substantial Equivalence Chart

Feature	Avid Care K011779	Philips K023749	Carematix
Indications of Use	Enables healthcare providers to manage chronic conditions of patients remotely	Same	Same
Intended use	Telemedicine System	Same	Same
Intended Users	Home users and Health care provider	Same	Same
Site of Use	Home; clinic	Same	Same
Software	Patient Database	Same	Same
Types of Sensors	Blood Pressure Weight Glucose levels Oxygen Saturation PT/INR FEV/PEF	Blood Pressure Weight Glucose levels ECG	Blood Pressure Weight Glucose levels
Power Source	Wall power plug for health monitor (hub) and Standard batteries in devices	Same	Same
Communication method with devices	Wired – over serial port	Wireless RF protocol	Wireless RF protocol
Communication method with central server	Via modem over telephone line	Same	Same
Display	On devices, and monitors connected to central server	Same	Same

7. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Carematrix, Inc.
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K031840
Trade Name: Carematrix Wellness System
Regulation Number: 21 CFR 870.1130 and 870.2910
Regulation Name: Noninvasive Blood Pressure Measurement System and Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXN and DRG
Dated: September 17, 2003
Received: September 22, 2003

Dear Mr. Kamm:

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) 594-4646. 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,

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 K031840

Device Name: Carematix Wellness System

Indications for Use:
The Carematix Wellness System is intended for patient home use for the following:

Non-invasive blood pressure measurement;
Measurement of blood glucose;
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.

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)

Melissa Mayo for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031840

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)