



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 2, 2015

Sanitas, Inc.
c/o Mr. Alan Donald, MS, MBA, FRAPS
President
Matrix Medical Consulting, Inc.
11440 W. Bernardo Court, Suite 300
San Diego, CA 92127

Re: K132173
Trade/Device Names: Family Healthware™
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (Two)
Product Code: DRG
Dated: April 27, 2014
Received: April 30, 2014

Dear Mr. Donald:

This letter corrects our letter of May 30, 2014.

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.

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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/ucml15809.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

4 Indications for Use Statement

510(k) Number: K132173

Device Name: Family Healthware™

Indications For Use:

Family Healthware™ is a self-administered, interactive Web-based tool that assesses familial risk for six diseases (coronary heart disease, stroke, diabetes, and colorectal, breast, and ovarian cancer) and provides personalized recommendations for lifestyle changes and screening.

Prescription Use _____ AND/OR Over-The-Counter Use **XX**
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5 510(k) Summary of Safety and Effectiveness

Device / trade name: Family Healthware™
Device type / Common Name: Telemedicine System
510(k) owner: Sanitas, Inc.
1640 El Camino Del Teatro
La Jolla, CA 92037
Phone: 858 945 0660
Contact: Mr. Naser Partovi, CEO

Establishment registration number: 3010209421

Authorized Contact Person:
Mr. Alan Donald, MS, MBA, FRAPS
Matrix Medical Consulting, Inc.
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San Diego, California 92127-1644
Phone: 858 485 8584
Fax: 858 753 1801

Recommended regulation: 21 CFR 870.2910

Device classification name: Radiofrequency physiological signal transmitter and receiver

Device class: Class II device

Panel: Cardiovascular Devices

Product code: DRG

Predicate device: Wellaho Personalized Outpatient Management System

Predicate Device Pro Code DRG

Predicate K 123671

Date Summary Prepared: May 25, 2014

Device Description:

Family Healthware™ is a Web-based software tool that can be used to assess a person's familial risk for six diseases (coronary heart disease, stroke, diabetes, and colorectal, breast, and ovarian cancer). It provides users with a "prevention plan" containing personalized recommendations for lifestyle changes and screening. For each person, the tool collects data about the following:

- Health behaviors (e.g., smoking and exercise),
- Screening tests (e.g., blood cholesterol and mammography),
- Health history among his or her first- and second-degree relatives.

One set of algorithms in the software analyzes users' family history data and assesses their familial risk for each of the six diseases. A second set of algorithms uses the data on familial risk, health behaviors, and screening results to generate personalized prevention messages.

The intended use is to utilize computerized family genomic data to increase disease risk perceptions and improve chronic disease management, thereby reducing the effects of these serious chronic disorders.

Indications for Use:

Family Healthware is a self-administered, interactive Web-based tool that assesses familial risk for six diseases (coronary heart disease, stroke, diabetes, and colorectal, breast, and ovarian cancer) and provides a "prevention plan" with personalized recommendations for lifestyle changes and screening.

Substantial Equivalency

Comparison Table of New and Predicate Device

A summary of the equivalence between the Sanitas Family Healthware and the Wellaho Personalized Outpatient Management System predicate device is given in the following table.

Parameter	Family Healthware (new)	Wellaho (predicate)
Intended Use	Telemedicine System	Telemedicine System
Intended Users	Home users and healthcare providers	Home users and healthcare providers
Site of Use	Any place with remote internet access	Any place with remote internet access
Purpose	To motivate patients to implement and maintain healthy life changes.	To motivate patients to implement and maintain healthy life changes.
Disease focus	Six specific chronic conditions	Chronic conditions
Advice provided	Healthy lifestyle changes linked to hereditary diseases	Healthy lifestyle changes
Rx or OTC?	OTC	OTC
Browser function available?	Yes	Yes
Smart phone app available?	No	Yes

Data collection platform	Internet	Internet
Data Collection Software	Proprietary software	Proprietary software
Data collection software functionality	Transmit data from device to central database	Transmit data from device to central database
Communication Technology	Wireless RF protocol, Internet	Wireless RF protocol, Internet
Communication Methods	Wi-Fi	Cellular modem, Wi-Fi
Internal Communication	Secure sockets Layer (SSL) via HTTPS	Secure sockets Layer (SSL) via HTTPS
Patient Feedback	Provides patient health reinforcement messages	Provides patient health reinforcement messages
Communication frequency	2.4 GHz	2.4 GHz

Communication via?	cellular modem, wifi	cellular modem, wifi
Communication with patients	On screen display	On screen display
Patient data on servers	Encrypted	Encrypted
Server to Browser communication	Encrypted	Encrypted

SE Discussion.**Product Classification**

Both devices have the same product classification (§870.2910).

Product Code

Both devices have the same Product Code (DRG).

Intended Use

Both devices have the same intended use (as telemedicine systems).

Indications for Use

Both devices have nearly the same indications for use.

User Safety

In terms of user safety, similar devices have been utilized for many years with a good record of safety. The technologies used within the Family Healthware software and the Wellaho Personalized Outpatient Management System are the same as those in other legally marketed risk assessment devices, and they are used for similar reasons in similar manners. There are no new additional safety concerns raised by these technologies. In addition, neither device is intended as a replacement for the oversight of healthcare professionals nor does either provide “real-time” or emergency monitoring.

Conclusions

The Family Healthware software uses the same fundamental technologies as the predicate device and has the same intended use and indications for use. The fundamental purpose of both devices is as outpatient risk assessment/management systems.

The Family Healthware software is substantially equivalent to the predicate device, the Wellaho Personalized Outpatient Management System, since their intended uses are the same, their indications for use are essentially the same, and they utilize similar technologies.

Based on the comparison of intended use, indications for use, and technological characteristics, the Family Healthware software is substantially equivalent to the Wellaho Personalized Outpatient Management System (K123671), with respect to intended use, indications for use, performance and technological characteristics. The Wellaho Personalized Outpatient Management System raises no new safety or effectiveness issues.