DEC - 2 2011

510(K) Summary

K111922

VoCare, Inc.
VoCare MyHealth Tablet™

Premarket Notification

SUBMITTED BY	VoCare, Inc. Purdue Technology Center 5225 Exploration Drive Indianapolis, IN 46241 USA
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	Pending
CONTACT PERSON	Primary Steve Peabody CEO and President VoCare, Inc. Phone: 317.973.1003 Fax: 765.482.5003 Alternate Ed Leer Chief Information Officer VoCare, Inc. Phone: 317.973.1003 Fax: 765.482.5003
SUBMISSION PREPARED BY	Bonnie Butner VoCare, Inc. Phone: 317.973.1003
DATE PREPARED	June 22, 2011
CLASSIFICATION NAME	Transmitters and Receivers, Physiological Signal, Radiofrequency
DEVICE CLASS	Class II
REGULATION NUMBER	870.2910 (Product Code DRG)
COMMON NAME	Remote Patient Monitoring System
PROPRIETARY NAME	VoCare MyHealth Tablet™
IDENTIFICATION OF PREDICATE DEVICE(S)	Predicate devices include: - Intel Health Guide PHS6000 (K080798) - MedApps 2.0 (K083862) - Waldo Health Waldo Patient Monitor (K110334)

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DEVICE DESCRIPTION

The VoCare MyHealth Tablet™ is a remote patient monitoring device available via prescription.

The VoCare MyHealth Tablet™ connects to commercially available wireless and tethered glucose meters, weight scales, blood pressure monitors and pulse oximeters, stores and displays the information on the LCD screen and transmits the information to the VoCare secure server. Healthcare professionals can review the transmitted information utilizing the VoCare Clinician Access System.

The VoCare System consists of:

1. VoCare System Hardware:

   The physical component of VoCare System is the VoCare MyHealth Tablet™, which is an electronic device contained in an acrylonitrile butadiene styrene (ABS) thermoplastic enclosure with a touch screen, built-in video camera, microphone, speaker, and a reminder light mounted on top left corner of the case. The VoCare MyHealth Tablet™ contains front and back panels that provide standard USB 2.0 connectors, Ethernet connector, power connector and power button, as well as volume controls.

2. VoCare MyHealth Tablet™ Software Application:

   The VoCare MyHealth Tablet™ executes the VoCare MyHealth Tablet™ Software Application, which connects to commercially available wireless and tethered glucose meters, weight scales, blood pressure monitors and pulse oximeters, stores and displays the information on the LCD screen and transmits the information to the VoCare secure server.

3. VoCare Clinician Access System (CAS) Software Application:

   The VoCare Clinician Access System (CAS), which is associated with and manages multiple VoCare MyHealth Tablet™ devices, is designed to allow doctors and nurses to create and access electronic health records as well as provide a user-friendly interface into a patient's health condition.

The VoCare System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The system is contraindicated for patients requiring direct medical supervision or emergency intervention. The system is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

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INDICATIONS FOR USE

The VoCare MyHealth Tablet™ is a remote patient monitoring device. The VoCare MyHealth Tablet™ connects to commercially available wireless and tethered glucose meters, weight scales, blood pressure monitors and pulse oximeters. The VoCare MyHealth Tablet™ stores and displays the information on the LCD screen and transmits the information to the VoCare secure host server using connectivity including, but not limited to, FCC approved Wi-Fi, or Ethernet.

Healthcare professionals can review the transmitted information utilizing the VoCare Clinician Access System and set thresholds to trigger alerts based on specific thresholds being exceeded.

The VoCare System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The system is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

A list of devices that are compatible with the VoCare System will be available in the user's manual and the VoCare website.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The VoCare System is substantially equivalent to the predicate devices in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source and display method.

DISCUSSION OF NON-CLINICAL TESTING

Non-clinical testing consisted of bench testing using VoCare procedures and specifications, usability testing under duplicated operating conditions and performance standards testing in accordance with IEC 60601-1 and IEC 60601-1-2. The results demonstrated that the VoCare System met performance and design specification requirements.

CONCLUSIONS

The subject and predicate device(s) are substantially equivalent in terms of intended use and technological characteristics. Non-clinical mechanical test results demonstrate that the VoCare System performance is satisfactory and suitable for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 2 2011

VoCare, Inc.
c/o Mr. Steve Peabody
CEO and President
Purdue Technology Center
5225 Exploration Drive
Indianapolis, IN 46241

Re: K111922
Trade/Device Name: VoCare MyHealth Tablet™ (Remote Patient Monitoring System)
Regulation Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: Class II (two)
Product Code: DRG
Dated: October 31, 2011
Received: November 1, 2011

Dear Mr. Peabody:

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,

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 (if known): K111922

Device Name: **VoCare MyHealth Tablet™**

Indications for Use:

The VoCare MyHealth Tablet™ is a remote patient monitor device available by prescription. The VoCare MyHealth Tablet™ is designed to be used in the home of a patient undergoing remote monitoring for maintenance of chronic disease. The VoCare MyHealth Tablet™ provides guidance in operating medical sensor devices, reminders for medication compliance and connectivity to healthcare professionals through text messaging and real-time video conferencing technology.

The VoCare MyHealth Tablet™ connects to commercially available wireless and tethered glucose meters, weight scales, blood pressure monitors and pulse oximeters. The VoCare MyHealth Tablet™ stores and displays the information on the LCD screen and transmits the information to the VoCare secure host server using FCC approved Wi-Fi or Ethernet.

Healthcare professionals can review the transmitted information utilizing the VoCare Clinician Access System and set thresholds to trigger alerts based on specific thresholds being exceeded.

The VoCare System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The system is intended for patients who are willing and capable of managing its use. Judgment and experience by a caregiver or by a family member are required to check and interpret the information delivered.

A list of devices that are compatible with the VoCare MyHealth Tablet™ will be available in the user's manual and the VoCare website.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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 K111922

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