K103069

JAN 28 2011

510(k) Summary

Submitted by SentiCare, Inc.
Address: 132 Turnpike Road, Suite 130
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Contact Name: Yogendra Jain, Chief Technical Officer / Co-founder

Date Submitted: January 18, 2011

Trade Name: SentiCare PillStation
Common Name: Medication reminder

Product Code / Regulation: 21 C.F.R. 890.5050, Daily Activity Assist Device (Medication Reminder), product code NXQ, class I

Description: The SentiCare PillStation includes an electronic pillbox for home use (the PillStation), and server software for communicating and programming the PillStation (PillStation Manager Software). The SentiCare PillStation is designed to assist individuals with medication organization, self administration, and adherence. Specifically, the PillStation is designed to aid individuals in medication organization and reconciliation; identify incomplete or inappropriate removal of medications with corrective feedback; teach and coach about medications and daily medical procedures; provide alerts of dose times; and ensure timely refills of all medications self-administration. The SentiCare PillStation is a daily assist device with many features to alert users and caregivers of pre-determined scheduled medication times: easy to use pill tray, pill bins highlighted by light-up indicators, pill alarms, and LCD screen messaging. Through PillStation's built in scanning system, high quality, static digital images are sent from the PillStation to PillStation Manager software. Remote monitors, people called "Call Center Advisors", monitor and verify PillStation's medication contents with PillStation users' prescriptions in order to keep track of medication alerts and verify that the user and/or caregiver has loaded their prescribed medications into the PillStation pill tray. This monitoring is accomplished through the PillStation Manager software. The SentiCare PillStation is a novel approach to medication organization and may be of great assistance to those individuals and caregivers who look to improve upon their own medication organization, adherence, and self administration.

Intended Use: The SentiCare PillStation is intended for medical purposes to provide alerts to patients and healthcare providers for pre-determined medication dosing schedules. The device incorporates wireless communication and electronic imaging.

Substantial Equivalence: The SentiCare PillStation is similar in intended use and technological characteristics to predicate devices reviewed as

medication reminders (Daily Activity Assist Devices), including the Vocel Pill Phone (K060298), and the e-pill® 4 Alarm Vibrating Pill Box (510(k) exempt).

The capability of the SentiCare PillStation to image the contents of the pill tray and upload the information through the Internet to a central server was determined by the FDA to introduce a different fundamental technology requiring the submission of a 510(k). Despite the introduction of this technology into the device, the SentiCare PillStation does not perform image recognition or prohibit access to medications stored in the device. Apart from the additional capability to scan the contents of the pill tray, the SentiCare PillStation is otherwise similar with respect to indications for use and physical characteristics to predicate devices in terms of 510(k) substantial equivalency.

Applicable tests were carried out as part of the software design process, where the key functions of the SentiCare PillStation (including both the PillStation and the PillStation Manager software) were verified and/or validated. The results of the testing met specifications, and established the device as safe and effective for its intended use, which is comparable to other predicate devices.

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

SentiCare, Incorporated
C/O Mr. Seth A. Mailhot
Nixon Peabody LLP
401 9th Street NW, Suite 900
Washington, District of Columbia 20004

JAN 28 2011

Re: K103009
Trade/Device Name: SentiCare PillStation
Regulation Number: 21 CFR 890.5050
Regulation Name: Daily Activity Assist Device
Regulatory Class: I
Product Code: NXQ
Dated: January 18, 2011
Received: January 19, 2011

Dear Mr. Mailhot:

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.

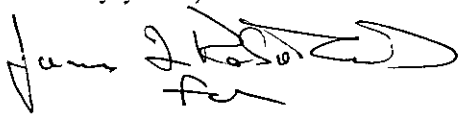
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: SentiCare PillStation

Intended Use:

The SentiCare PillStation is intended for medical purposes to provide alerts to patients and healthcare providers for pre-determined medication dosing schedules. The device incorporates wireless communication and electronic imaging.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

1/26/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103009