K101109

Pre Market Notification 510(k) Summary

1. **Sponsor Information:**

Company Name & Address: Wireless MedCARE, LLC.
15 E. Salem Ave., Suite 201
Roanoke, VA 24011

JUL 15 2010

Contact Person: Kenneth D. Ferris
Contact Title: COO
Contact Phone Number: 540-520-8707
Contact Fax Number: 540-344-2966

Date of Summary: April 9, 2010

2. **Device Name and Classification:**

Common and Usual Name: Monitor, Bed Patient

Proprietary Name: VivaTRAK™

Classification Name: Bed-Patient Monitor
Classification Regulation: 21CFR 880.2400
Device Classification: Class 1
Product Code: KMI

Performance Standards: No applicable performance standards have been issued under section 514 or under section 513 (b) of the Food, Drug and Cosmetic Act.

3. **Predicate Device(s):**

AFrame Digital, Inc., AFrame MobileCare Monitor (K090138),
Stanley Security Solutions, Inc., TABS Elite (Class 1, 510(k) Exempt)
Stanley Healthcare Solutions, Roll-Check (Class 1, 510(k) Exempt)
Home Guardian, WellAWARE Systems (Class 1, 510(k) Exempt)
Emfit Ltd., SafeBed (Class 1, 510(k) Exempt)

4. **Description of Device:**

The VivaTRAK™ system is used for monitoring in-bed patient activity and care delivery. The system monitors in-bed patient activity with the BedSense sensor, an under-the-mattress activity sensing pad, processing and wireless transmission of activity data with the ActivSense™ Bed Computer, and providing pager, email, phone and display notifications and care reports to the nursing staff, and then verifying using RFID readers that care was actually delivered with the VivaTRAK™ application. Care reports consisting of a notification, a RFID scan and bed activity are stored in a database and form the basis for reports used to improve quality of care and work flows at the facility.

5. **Indications for Use:**
The VivaTRAK™ system monitors in-bed activity and care delivery for patients susceptible to pressure ulcers and falls as well as those that require 24 hour monitoring of their general activity levels in medical, nursing and long-term care facilities including independent living, assisted living and rehabilitation facilities. The system provides care providers information related to patient status and care delivered.

The VivaTRAK™ system is not intended to provide automated treatment decisions or used as a substitute for professional healthcare judgment. The VivaTRAK™ system is not a replacement or substitute for vital signs monitoring or alert equipment. All patient medical diagnosis and treatment are to be performed under direct supervision and oversight of an appropriate health care professional.

6. **Comparison with Predicate Device (s):**
The VivaTRAK™ system is substantially equivalent to the predicate devices (AFrame Digital, Inc.'s AFrame MobileCare Monitor™, Stanley Security Solution's TABS Elite, Stanley Healthcare Solution's Roll-Check™, Home Guardian's WellAWARE™ Systems, and Emfit Ltd's SafeBed).

VivaTRAK™ is similar in characteristics, features, technological features, intended use, and indications for use, as the predicates. Any differences in the technology used when compared to the predicates have been satisfactorily addressed by conformance to FDA and Internationally recognized safety consensus standards as well as, to the company's design requirements. The VivaTRAK™ system is as safe and effective as the predicate devices.

7. **Non-Clinical Performance Summary:**
Wireless MedCARE has verified and validated that the VivaTRAK™ system meets its functional, performance, safety, and efficacy specifications and requirements.

8. **Conclusions:**
In summary, Wireless MedCARE is of the opinion that the VivaTRAK™ system is as safe and effective as similar devices currently on the market, and concludes that the VivaTRAK™ is substantially equivalent to the predicate devices and those 510(k) exempt products being marketed in U.S. interstate commerce.

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

Wireless MedCARE, LLC
C/O Mr. Paul Sumner
Arkin Consulting Group
1733 Canton Lane
Marietta, Georgia 30062

JUL 16 2010

Re: K101109
Trade/Device Name: VivaTRAK™
Regulation Number: 21 CFR 880.2400
Regulation Name: Bed-Patient Monitor
Regulatory Class: I
Product Code: KMI
Dated: July 7, 2010
Received: July 8, 2010

Dear Mr. Sumner:

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,

for

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

4 Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): N/A

Device Name: VivaTRAK™

Indications for Use:

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Prescription Use _____ (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 OF NEEDED)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
510(k) Number: K101109