WIRELESS2000
RF & UWB Technologies Ltd

510(k) Summary
(per 21 CFR 807 92)

JAN 16 2009

I. Applicant

Wireless 2000 RF & UWB Technologies Ltd
2421 Alpha Ave
Burnaby, BC, V5C5L2

Contact Person Efraim Gavrilovich, President and CEO
Tel (604) 298-8471
Fax (604) 298-8470
Email egav@wireless2000 com

Date Prepared August 27, 2008

II. Device Name

Proprietary Name	PAM™ 3000
Common/ Usual Name	Heart Rate and Respiration Rate Monitor
Classification Name	monitor, cardiac (incl cardiotachometer & rate alarm) monitor, breathing frequency
Regulation Number	870 2300/868 2375
Product Codes	DRT/BZQ
Classification	II
Classification Panel	Cardiovascular/Anesthesiology

III. Predicate Device

The Wireless 2000 PAM™ 3000 is substantially equivalent to the EarlySense ES-16 System from EarlySense Ltd (K070375) and LG1™ Intelligent Medical Vigilance System from Hoana Medical Inc (K052446)

IV. Intended Use of the Device

The PAM™3000 system is intended to measure heart rate and respiration rate in adult patients, in a general care hospital environment including, nursing homes The system monitors presence or absence of a patient in bed (bed exit) The system also times the length of continuous patient motion or absence of patient motion

V. Description of the Device

The PAM™3000 System is intended for contact-less and wireless monitoring of bed occupancy, motion and heart and respiration rates of adult patients in healthcare facilities The system utilizes a highly sensitive UWB-based motion sensor to detect the motion of heart and thorax The system consists of

a Bed Sensor Panel (BSP), placed under the patient's mattress, Repeater Base Stations (RBS) that are typically mounted around the hallways in facility, and the Central Computer Station (CCS) with plugged-in Central Base Station (CBS) The signal containing the patient's heart rate and respiration rate data, bed occupancy data, patient motion, and the alerts generated by system are displayed on a PC monitor using Wireless 2000's proprietary Graphic User Interface (GUI) software The Central Computer Station (CCS) is typically located at the nursing station

VI. Summary of the Technical Characteristics

Measurement Range		
Heart Rate	Normal	45-115 beats per minute
	Elevated	85-170 beats per minute
Respiration Rate	Normal	3-30 breaths per minute
	Elevated	3-50 breaths per minute

VII. Safety & Effectiveness

The PAM™3000 System was designed and tested using the following standards

- IEC 60601-1 (2nd Edition) Medical Electrical Equipment --Part 1 General Requirements for Safety
- IEC 60601-1-2 (3rd Edition) Medical Electrical Equipment - Part 1 General Requirements For Safety 2 Collateral Standard Electromagnetic Compatibility
- FCC Part 15 207/209/517 Conducted limits / Radiated emission limits, general requirements / Technical requirements for indoor UWB systems
- ANSI C63 4 2003 Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz
- IEC 62-2- 27 Shock Peak acceleration 100 g (980 m/s2), Duration 6 msec, Pulse shape half sine
- IEC 68-2-6 Sinusoidal Vibration Frequency range 10 to 500 Hz, Acceleration amplitude 1 g (9 8 m/s2), Type and duration of endurance 10 sweep cycles in each axis
- IEC 68-2-34 Random Vibration (Wide band) Frequency range 20 Hz - 500 Hz, Acceleration spectral density 0 02 g2/Hz, Degree of reproducibility low, Duration of conditioning 9 minutes

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In addition, the PAM™ 3000 System underwent bench validation testing and clinical validation testing The results of the testing indicate that the PAM™3000 performs according to its specifications and accurately detects respiration rate and heart rate of patients and patient presence in bed

Overall there are no known substantial differences between the PAM™ 3000 system defined in this 510(k) submission and the predicate devices The devices have the same intended uses and any differences in technological characteristics do not raise issues of safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2009

Wireless 2000 RF and UWB Technologies, Ltd
c/o Mr Efraim Gavrilovich
President & CEO
2421 Alpha Ave
Burnaby V5C5L2 Canada

Re K082626
PAM 3000
Regulation Number 21 CFR 870 2300
Regulation Name Heart rate monitor, cardiac (incl cardiotachometer and rate alarm)
Regulatory Class II
Product Code DRT
Dated December 16, 2008
Received December 22, 2008

Dear Mr Gavrilovich

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 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 (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Bram D Zuckerman, M D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indication for Use Statement

510(k) Number (if known):

Device Name: PAM™ 3000

Indications for Use:
The PAM™3000 system is intended to measure heart rate and respiration rate in adult patients, in a general care hospital environment including, nursing homes The system monitors presence or absence of a patient in bed (bed exit) The system also times the length of continuous patient motion or absence of patient motion

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

for BZuckerman

(Division Sign-Off) 1/16/09
Division of Cardiovascular Devices

510(k) Number K082626