K083715

SEP 15 2009

BeltBeat
510(k) Summary of Safety and Effectiveness

Submitter	**Bonus Comunicaciones SRL**	
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Device		
Trade Name:	BeltBeat	

Regulation No.	Class	Product Code	Regulation Description
870.2300	II	DRT	Cardiac monitor (including cardiotachometer and rate alarm)
870.2910	II	DRG	Radiofrequency physiological signal transmitter and receiver.

Device Definition

The BeltBeat is a comprehensive ambulatory system solution for ECG monitoring in intermediate care units for adult and pediatric patients. The foundation of the system is a transmitter (BeltBeat WF400) that can capture and transmit ECG signals that are then processed and displayed on the Information Center (BealtBeat STC). The Information Center generates alarms and recordings, thus notifying clinicians of changes in patients' conditions.

The monitoring software BeltBeat STC displays in a computer screen ECG waveforms and heart rate numerics, and may be configured to generate patient alarms and alert messages. Additionally, full recording of patient data is available. The software is capable of monitoring up to 12 patients (BeltBeat WF400 units) simultaneously.

BeltBeat system is intended for 5-lead ECG monitoring.

The most likely locations for patients monitored by this system are: cardiac rehabilitation facilities, postoperative recovery rooms, ambulatory surgery, intermediate care, emergency departments, telemetry departments and in-hospital transport.

This system is not intended for home use, or any other use outside health care facilities.

BeltBeat WF400 monitor is not intended for use with pediatric patients (or infants) weighing less than 22 lbs (10 kgs).

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Referenced Standards

- EC13:2002/(R)2007
- 60601-1-4 +A1:2000
- 60601-2-27:2005
- ISO 13485:2003
- ISO 14971:2007

Indications for Use, Intended Use

This monitoring system is intended to be used by clinicians for ECG signals monitoring of ambulatory and nonambulatory adult and pediatric patients in health care facilities. This product is intended to be used by trained health care professionals. It is not intended for home use.

Principles of operation

This monitoring system is intended to be used by clinicians for ECG signals monitoring of ambulatory and nonambulatory adult and pediatric patients, in health care facilities.

A patient wearable device BeltBeat WF400 acquires ECG signals and transmits them through a Wireless Local Area Network (WLAN), to be processed and displayed by the monitoring software BeltBeat STC. Patient should therefore remain within a defined WLAN coverage area, in order not to interrupt the ECG signals transmission and recording.
Wireless technology provides flexibility and freedom of movement, increasing the patient's comfort.

- Time Optimization, since every central station allows up to 12 patients to be monitored simultaneously.
- Flexibility, the system can be configured to adapt to every users' needs.
- *Safety and Control, by means of patient alarms and alert messages.*
- Stand-by mode available, for energy saving.
- Versatility of printing. Several parameters can be configured before printing reports.

BeltBeat is a telemetric cardiac monitoring system, designed with state-of-the-art technology for acquisition and display of ECG signals. A standard wireless connection allows real-time transmission to a monitoring central station.
Multiple leads of up to 12 patients can be monitored simultaneously, and different configurations can be selected in a simple manner.

Full recording of patient data is also available, allowing physicians to analyze cardiac signals off-line.

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Substantially Equivalent Devices

1. "Welch Allyn Micropaq Monitor (Model 406 / 408) Software version 1.6X + Acuity Central Station"
2. "Philips Transmitters M2601B + IntelliVue Information Center (Philips Telemetry System)"

Conclusions

All Verification, Validation and Testing (VV&T) documents - constitute a part of the device DMR and *are available upon request.*

The Truthful and Accurate Statement complies with 21 CFR 807.87(j).

We trust that the submitted information will enable the reviewer to process the material promptly. The time factor is crucial for Bonus' commercial interests.

This dossier contains one paper copy of the 510(k) submission together with an electronic copy that is an exact duplicate of the paper copy.

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

SEP 15 2009

Bonus Comunicaciones SRL
Mr. Héctor Foggia
Regulatory Affairs Manager
Fonrouge 1561
Ciudad Autonoma de Buenos Aires
Argentina C1440CYO

Re: K083715
Trade/Device Name: BeltBeat
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS, DRG and DRT
Dated: Undated
Received: September 09, 2009

Dear Mr. Foggia:

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 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 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):

Device Name: BeltBeat

Indications for Use:

This monitoring system is intended to be used by clinicians for ECG signals monitoring of ambulatory and nonambulatory adult and pediatric patients in health care facilities. This product is intended to be used by trained health care professionals. It is not intended for home use.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083715