DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 30, 2015

Vitasystems Gmbh
% Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K151013
Trade/Device Name: Vitaphone Post-Event Recorder 300 BT
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: II (two)
Product Code: DXH
Dated: April 13, 2015
Received: April 15, 2015

Dear Mr. Mark Job,

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.

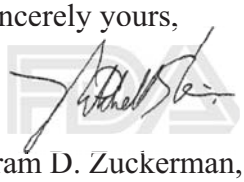
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

510(k) Number (if known): __K151013_____

Device Name: ___ Vitaphone Post-Event Recorder 300 BT_____

Indications For Use:

Diagnostic evaluation of patients with asymptomatic and symptomatic disturbances of cardiac rhythm such as:
-Dizziness
-Heart race
-Palpitation
-Syncopes of unknown cause

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

510(k) Summary
Prepared June 30, 2014

Sponsor: Vitasystems GmbH

Address: Staderstralle 14
D-09126 Chemnitz, Germany

Contact Person: Michael Rothhaar

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Submission Date: June 30, 2014

Device Name: Vitaphone Post-Event Recorder 300BT

Common Name: Tele-ECG System, Cardiac Event Recorder

Classification:
Regulatory Class: II
Review Category: Tele-ECG System, Cardiac Event Recorder
21CFR 870.2920 (DXH)
Classification Panel: Cardiology

A. Legally Marketed Predicate Devices

The Post Event 300BT device is substantially equivalent to Vitaphone's Post Event Recorder 100BT (K100383) with regard to both its intended use and its core technological characteristics. The 300BT represents a modification to the predicate device.

B. Device Description:

The ECG monitoring devices are post-event recorders, also called tele-ECG devices, which realize one-channel (100BT) or three- channel (300BT) recordings of short ECG sections, their memorization as well as the preparation of the data for the transmission. Therefore, the purpose of the recorders is the derivation and memorization of an ECG section in combination with a compatible telemedicine system. The recorder provides physicians with information used for the diagnosis of cardiac arrhythmias. The Post Event 300BT device is a modification to Vitaphone's previously cleared Post Event 110BT device cleared pursuant to K100383.

The modification consists of the availability of three recording channels rather than one recording channel. There is no change to intended use, patient contact materials or core

technology. The hardware of the 100BT and the 300BT is basically the same. The differences between both devices is the activation of the channels by the software. The device supports the transmission of the data. The recorders are battery operated devices. The recorders do not possess a separate on/off switch.

C. Intended Use

Diagnostic evaluation of patients with asymptomatic and symptomatic disturbances of the cardiac rhythm such as:
-Dizziness
-Heart race
-Palpatations
-Syncopes of unknown cause

D. Substantial Equivalence

The Post Event 300BT device is substantially equivalent to Vitaphone's previously cleared Post Event 100BT device cleared pursuant to K100383. There is only one difference between the original and the modified device: the 300BT provides 3 recording channels whereas the 100BT had only one recording channel. There is not change to the intended use, materials or core technology. A comparison between the predicate and the modified device and an analysis of the differences demonstrated that the devices are substantially equivalent.

Feature	Predicate Device Vitaphone 100BT Event Recorder (K100383)	Subject Device Vitaphone 300BT Event Recorder
Intended use	Diagnostic evaluation of patients with asymptomatic and symptomatic disturbances of the cardiac rhythm such as: – Dizziness – Racing heart beat – Palpitations – Syncopes of unknown cause	Diagnostic evaluation of patients with asymptomatic and symptomatic disturbances of the cardiac rhythm such as: – Dizziness – Racing heart beat – Palpitations – Syncopes of unknown cause
Intended Users	Healthcare Professionals	Healthcare Professionals
Class	II	II
Regulation number Code	21CFR 870.2920	21CFR 870.2920
Device Description	The Vitaphone 100 BT device is a one channel cardiac event recorder for transmitting multiple ECG recordings via land-line or GSM telephony networks to a compatible ECG receiving system, such as REMOS ECG Receiving Software (510(k) K050670) or compatible ECG receivers. The Vitaphone 100 BT device is intended for patient activated event recordings. It is battery operated and Utilizes a Flash memory to store ECG data with and adjustable event time.	The Vitaphone 300 BT device is a three channel cardiac event recorder for transmitting multiple ECG recordings via land-line or GSM telephony networks to a compatible ECG receiving system, such as REMOS ECG Receiving Software (510(k) K050670) or compatible ECG receivers. The Vitaphone 300 BT device is intended for patient activated event recordings. It is battery operated and utilizes a Flash memory to store ECG data with an adjustable event time.

Comparison Table – Technological Characteristics

Feature	**Predicate Device** **Vitaphone 100BT Event Recorder (K100383)**	**Subject Device** **Vitaphone 300BT Event Recorder**
ECG Channels	1	3
Safety	Compliant with ISO 60601-1	Compliant with ISO 60601-1
Display	Yes	Yes
Buttons	2	2
Audible feedback	Yes	Yes
Setup	Use of buttons and display	Use of buttons and display
Transmission method	Bluetooth / GSM; transtelephonic	Bluetooth / GSM; transtelephonic
Audio trigger	No	No
Arythmia detection	No	No
Auto send	Yes	Yes
Electrode type	Metal	Metal
Looping memory	No	No
Pacemaker detection	Yes	Yes
Applied part class	BF	BF
ECG memory	10800s	10800s
Max events	120	120
Batteries	2 x AAA	2 x AAA
Battery lifetime	100 ECG transmissions	100 ECG transmissions
Backup battery	Yes	Yes
Weight	95 gr	95 gr
Width	74 mm	74mm
Thickness	23mm	23mm
Cover material	Molded plastic	Molded plastic
Operating temperature	5-45°C	5-45°C
Storage temperature	-20 - +60° C	-20 - +60° C
Relative humidity	10-95%	10-95%
Memory type	Flash	Flash
Data retention	10 years	10 years
Sampling rate	200 Hz	200 Hz
A/D Converter	12 bit	12 bit
Input impedance	10 MOhm	10 MOhm
Frequency range	0.5 – 40 Hz	0.5 – 40 Hz
Signal input range AC	+/- 3mV	+/- 3mV
Signal input range DC	+/- 300 mV	+/- 300 mV
Common mode ejection	80dB	80dB
Amplitude	1 mV	1 mV

calibration		
Minimum feature size	50µV p-v@10Hz	50µV p-v@10Hz

E. Performance Data

Every specification of the modified device has been validated according to the documented development and test procedures. The verification and validation testing included testing to applicable standards including:

- Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1; 2005, MOD)
- Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility Requirements and tests
- Medical electrical equipment-Part 2-47; Particular requirements for the safety , including essential performance; of ambulatory electrocardiographic systems
- ISO 14971 Medical devices – application of risk management to medical devices

Verification and validation testing were completed in accordance with the company's design control process in compliance with 21 CFR Part 820.30. Results of performance testing demonstrated that the 300BT model is substantially equivalent to the 100BT and that the 300BT meets all performance specifications.