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APR 20 2010

510(k) Summary

Post-Event Recorder vitaphone 100 BT

Submitter: Vitasystems GmbH
Stadlerstraße 14
D-09126 Chemnitz, Germany
Phone: +49 371 40081 0
Fax: +49 371 40081 22

Contact Person:
Tilo Borchardt, CTO
Phone: +49 371 40081 122
Fax: +49 371 40081 22
Email: tb@vitasystems-gmbh.com

Establishment Registration Number: 3005191294

Trade Name: Vitaphone 100 BT

Common Name: Tele ECG System, Cardiac Event Recorder, Post-Event Recorder

Classification Name: Telephone electrocardiograph transmitter and receiver (per 21 CFR Section 870.2920, Product Code: DXH)

1. Predicate Devices

Device Type	Vitaphone 3100 BT	PMP4 SelfCheck ECG
Manufacturer	Vitasystems GmbH	Card Guard Ltd.
510(K) Number	K053378	K042254

Table 5-1

2. Intended Use

The Vitaphone 100 BT device is single-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 driven and utilizes a Flash memory to store ECG data with an adjustable event time.

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3. Device Classification

The system is classified as Class II medical device (21 CFR 870.2920).

4. Applicable Standards

- EN 60601-1:2006, "Medical Electrical Equipment, General Requirements for Safety"
- EN 60601-1-2:2007, "Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic compatibility – Requirements and tests"
- E DIN IEC 60601-2-47:2008, "Medical Electrical Equipment, Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems"
- ISO 10993-1:2003, "Biological Evaluation of Medical Devices, Evaluation and Testing"
- ISO 14971:2007, "Medical devices – Application of risk management to medical devices"
- ISO 13485:2007, "Medical Devices – Quality management systems – Requirements for regulatory purposes"

5. Substantial Equivalence

Through the data and information presented, Vitasystems GmbH considers the Vitaphone 100 BT as substantially equivalent to the previously mentioned predicate devices.
The operation of the Vitaphone 100 BT shows a safe and reliable means for recording and transmission of patient ECG parameters and no adverse health effect or safety risk to patients when used as intended.

Vitasystems GmbH
Tilo Borchardt
CTO

Signature: ..... Date: 2010-01-21

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Vitasystems GmbH
c/o Mr. Tilo Borchardt
Chief Technical Officer (CTO)
Stadlerstrasse 14
Chemnitz
GERMANY 09126

APR 20 2010

Re: K100383
Trade/Device Name: Post-Event Recorder Vitaphone 100 BT
Regulatory Number: 21 CFR 870.2920
Regulation Name: Transmitter and Receiver, Electrocardiograph, Telephone
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: February 14, 2010
Received: February 16, 2010

Dear Mr. Borchardt:

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.

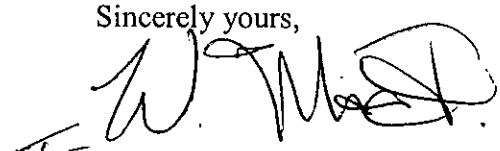
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

K100383

Indications for Use

510(k) Number (if known): _____

Device Name: Post-Event Recorder Vitaphone 100 BT

Indications for Use:

Diagnostic evaluation of patients with asymptomatic and symptomatic disturbances of the cardiac rhythm such as:

- Dizziness
- Heart race
- Palpitations
- Syncopes of unknown cause

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100383