Section 5

510(K) Summary of Safety and Effectiveness
Telemedical System "sensor mobile"

Submitter: TMS Telemedizinische Systeme GmbH
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Trade Name: Telemedical System „sensor mobile" SM100 , vitaphone 100IR, REMOS

Common Name: Tele ECG System, Event Recorder, ECG Recording Card

Classification Name: Telephone electrocardiograph transmitter and receiver (per 21 CFR Section 870.2920)

1. Intended Use

The telemedical system „sensor mobile" comprises the patient activated Tele-ECG device SM100 / vitaphone 100IR and the REMOS Receiving Software. The SM100 / vitaphone 100IR records and stores one-channel ECG episodes and transmits these data by means of a telephone or a mobile phone to a receiving station equipped with the REMOS Receiving Software for further processing.

2. Indications for Use

Symptomatic disturbances of cardiac rhythm such as palpitations, fatigue, heart racing, fluttering, chest discomfort or pain.

K050670
p 2/6

3. Contra-indications

The system is not for use as a critical care monitoring system. The device is not to be used with

- simultaneous defibrillation
- treatment using electrosurgical units or electrocoagulation
- too strong electromagnetic interference fields (aerials, high-voltage transformers, generators, NMR tomographs)
- external pacemakers

4. Device Class

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

5. Predicate Device

Predicate Device:	Manufacturer:	Predicate 510(K):
PHD™	Heart Alert, Inc.	K963904

6. Applicable Standards

- IEC 60601-1:1988, "Medical Electrical Equipment, General Requirements for Safety"
- IEC 60601-1-2:2001, "Medical Electrical Equipment - Part 1-2: General Requirements for Safety, Collateral Standard: Electromagnetic Compatibility"
- IEC 60601-1-4:1999, "Medical Electrical Equipment - Part 1-4: General Requirements for Safety, Collateral Standard: Programmable Electrical Medical Systems"
- IEC 60601-2-47:2001, "Medical Electrical Equipment - Part 2-47: Particular requirements for safety, including essential performance, for ambulatory electrocardiographic systems"
- ISO 10993-1:2003, "Biological Evaluation of Medical Devices, Evaluation and Testing"
- ISO 14971:2001, "Medical devices – Application of risk management to medical devices"
- ISO 13485:2003, "Medical Devices – Quality management systems – Requirements for regulatory purposes"
- "Off-The-Shelf Software Use in Medical Device", FDA, September 1999
- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", FDA, May 1998
- "General Principles of Software Validation; Final Guidance for Industry and Staff" FDA, June 1997

7. Operational Characteristics

The Tele ECG device "sensor mobile" SM 100 / vitaphone 100IR, manufactured by TMS, is capable of recording, storing and transmitting up to three ECG episodes of 30 seconds each. The "sensor mobile" SM 100 is placed on the chest for post-event recording. The device is patient activated by pressing the record button. The 30-second ECG is stored in the device memory for later acoustic transmission via telephone or mobile phone in form of digital data (FSK) or via infrared (IrDA) and IrDA-enabled mobile phone to a telemedical central station equipped with the "sensor mobile" Receiving Software REMOS.
The transmission is activated by pressing the send button. The device does not impair internal pacemakers and implantable cardioverters / defibrillators.

8. Predicate Device Comparison

Comparison (Feature / Spec)	**„sensor mobile“**	**PHD™**	**Explanation of Differences**
Length	90 mm	84 mm	
Width	53 mm	54 mm	
Thickness	8 mm	7 mm	
Weight	37 g	30 g	
Cover material *	Makrolon 2458 550115	Unknown Plastic	
Electrode material *	Steel, 316L 1.4404	Steel with unknown plating	
Batterie(s)	3 V, CR2032	3 V, CR2430	
Battery lasts approx.	5 Years	1 Year	Provides greater operational patient convenience
Backup-Battery	Not necessary	CR1220	
Operating Temperature	5 - 45 °C	10 - 40 °C	
Storage Temperature	-20 - +60 °C	-10 - +60 °C	
Relative Humidity	10 - 95 %	10 - 95 %	
Input Impedance	100 MOhm	100 MOhm	
CMRR	80 dB	60 dB	80 dB gives improved signal fidelity
Differential Range AC	6 mV	4 mV	
Differential Range DC	300mV	250 mV	

K050670
p 4/6

Comparison (Feature / Spec)	**„sensor mobile“**	**PHD™**	**Explanation of Differences**
Bandwidth	0,5 - 40 Hz	0,5 - 30 Hz	40 Hz gives improved signal fidelity
Resolution	6 mV	15,6 mV	Improved resolution
Recording Period	3x30s	3x30s	
Memory hold time	5 Years	128 days	Safety improvement
ECG lead	1	1	
ECG Recording	bipolar	bipolar	
Timer accuracy	max. 30 s / month	10s / month	No risk for patient safety, refer to risk analysis
AD accuracy	12 Bit	8 Bit	12 Bit gives improved ECG output quality
Pacemaker Spike Recognition	Yes	No	Provides better diagnostic capabilities
Defibrillator Protection	No	No	
Acoustic transmission	FSK	FSK, FM modulation	
Digital transmission	IrDA	none	Provides greater operational patient convenience
ECG output	PDF file format, 5mm grid	Unknown format	Extended capabilities for archiving and further processing
ECG Receiver	PC based Software	Hardware Receiver and PC based software	No use of proprietary hardware for „sensor mobile“ system
Operating System for Receiving Software	Linux	Windows	

Tab. 8.1

* Materials with contact to the skin of the user / patient.

9. Substantial Equivalence

The technical specification comparison reveals no substantial differerence between the "sensor mobile" system and the predicate device and no differences which affect safety or efficacy.

These devices are patient activated Cardiac Event Recorders that sense ECG signals from the skin surface. The method of placing the device on the skin has been used successfully by Heart Alerts's PHD™. The use of FSK encoding for transtelephonic transmission of

digital data is also used in the predicate device PHD™. The method of obtaining the ECG signal via metal contacts is identical.
The usage of the SM100 / vitaphone 100IR is also identical to the predicate device. The operational details are identical with the exception of the possibility of infrared / IrDA data transmission of the SM100 / vitaphone 100IR.

The "sensor mobile" Receiving Software REMOS receives the digital ECG data via telephone line and stores it into a database. The receiving software is designed for automatic operation 24 hours a day. The ECG data will be converted to a human readable output in PDF file format with anonymized patient / user information.
In the whole sending and receiving procedure is no substantial differerence between the telemedical system "sensor mobile" and the predicate device. Both systems are designed for transtelephonic transmission and uses software on the receiving side for further processing of the ECG data.

10. Summary of Non-Clinical Testing

The system „sensor mobile“ meets or exceeds the applicable requirements of international standards for ambulatory electrocardiographs and the safety requirements of IEC 60601-1 and its applicable follow-up standards.
Biocompatibility assessment was performed for any materials in contact with the skin of the user / patient.

11. Summary of Clinical Testing

TMS has performed clinical testing on the "sensor mobile" system. The system was tested with 80 patients suffering from different cardiac dysrhythmia or patients that are suspected of having cardiac dysrhythmia (patients subjectively feel palpitations or pauses). One hundred ECG examples of the eighty patients have been transmitted and interpreted.
98 percent of the received ECGs could be interpreted which can be rated as a very good achievement. Especially due to the technical recording, the basic rhythm (sinus rhythm, atrial fibrillation, atrial flutter, supraventricular (heart atrium) tachycardia, or nodal

K050670
P1/2

rhythm) could be detected with all the ECGs.
Furthermore, the function of pacemakers could be checked. The pacemaker spikes imaging and the reply of these spikes in the atrium or in the ventricle is good.
Another possibility was the determination of wide QRS complexes (in the sense of a bundle-branch block pattern) in ECG examples.
The device sensor mobile SM100 and the service meet clinical demands.

12. Conclusion

Through the data and information presented TMS Telemedizinische System GmbH considers the "sensor mobile" system as substantially equivalent to the previously discussed predicate device.
The operation of the "sensor mobile" system shows a safe and reliable means for recording, transmission, storing, forwarding and presentation of patient ECG parameters and no adverse health effect or safety risk to patients when used as intended.

TMS Telemedizinische Systeme GmbH
Joachim Schlund
Managing Director

Signature: ..... Date: 21.02.05

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2005

TMS Telemedizinische Systeme GmbH
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Re: K050670
Trade Name: Telemedical System "Sensor Mobile" SM100 / Vitaphone 100IR, REMOS
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DXH
Dated: February 28, 2004
Received: March 15, 2005

Dear Mr. Sammons:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zimmerman for

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

Enclosure

K050670

Indications for Use

510(k) Number (if known): _____

Device Name: Telemedical System „sensor mobile“ SM100 / vitaphone 100IR, REMOS

Indications for Use:

Symptomatic disturbances of cardiac rhythm such as palpitations, fatigue, heart racing, fluttering, chest discomfort or pain.

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)

B Hammond

ivision Sign-Off)
ivision of Cardiovascular Devices
10(k) Number K050670