4 510(k) Summary of Safety and Effectiveness

510(k) Summary MAR - 5 2004

510(k) number K033410

Submitter's name and address:

Remote Diagnostic Technologies Ltd (RDT),
The Old Coach House,
The Avenue,
Farleigh Wallop,
Basingstoke,
Hampshire,
RG25 2HT,
UK

Tel: 44 (0) 1256 362 400
Fax: 44 (0) 1256 362 415

Contact person: Mr Chris Hannan
Email: channan@rdtltd.com

Device: Tempus 2000 Patient Monitor
Tempus Monitoring Station

Classification: 74 DXH 21 CFR; 870.2920

Electrocardiograph
DPS 21 CFR; 870.2340

Non-invasive blood pressure measurement system
DXN; 21 CFR 870.1130

Oximeter
DQA; 21CFR 870.2700

Clinical electronic thermometer
FLL; 21 CFR 880.2910

Analyzer, carbon-dioxide, gaseous-phase
CCK; 21 CFR; 868.4100

4.1 Introduction

This pre-market submission covers the modification of an existing device, the Tempus 2000 Patient Monitor (part number 00-0001). The modification essentially provides increased flexibility of communications (the Tempus 2000 is a telemedicine product) by multiplexing the existing voice and data channels into a single channel. This enables communications over many more communications platforms e.g. medium-high bandwidth satellite terminals, whilst still maintaining all the ease of use features that the original device provided.

The modified product, the Tempus 2000 DSVD-GSM (part number 00-0002) will be marketed along side the original design.

As this submission is to support a modification, information from the original submission has been re-used where appropriate. It should be noted that where some whole passages have been repeated e.g. Intended Use is repeated as the statements remains unchanged by the modification, a statement is given to inform the reader that this is the case.

4.2 Intended Use

The Tempus 2000 Patient Monitor System is intended to be used when a medical situation arises at a location remote from readily available medical expertise. Situations demanding use of the Tempus 2000 Patient Monitor System can occur at remote land locations on private yachts while sailing at considerable distances from land, and during flight on commercial /private jets as well as in other situations.

The Tempus 2000 Patient Monitor is intended to be used by trained non-experts upon people presenting as unwell. It is designed with the most ease of use for the operator so that it can be used quickly, reliably, with minimum training and with little or no support from medical staff. This allows the Tempus 2000 Patient Monitor to be used as either a stand-alone monitor or also connected to the Tempus Monitoring Station. In the latter mode, the Tempus 2000 Patient Monitor connects to a sister device, called the Tempus Monitoring Station, allowing the recorded data to be viewed, stored and manipulated by trained medical staff.

The Tempus Monitoring Station is a normal, commercial grade PC which is dedicated to running the software that enables it to communicate with the Tempus 2000 Patient Monitor. The Tempus Monitoring Station is installed at a Response Centre (typically an emergency room within a hospital) and is operated by experts from the hospital staff. The operator at the Response Centre is able to receive voice calls and data on the patient's condition for assessment and consequently advise on an appropriate course of action. Such action may include advice on treatments to stabilize the condition, or instructions to return to land or divert from the planned journey, if the patient is at sea or in the air.

Note that the intended use of the product has not changed as a result of the modification detailed in this submission.

4.2.1 Indications/Contraindications

4.2.1.1 Indications

The Tempus 2000 Patient Monitor is a patient monitor intended to be used in remote locations where medical staff may not be present.

The device is intended to be applied to the patient by a trained operator who is not a medical expert. The device is not intended to allow the operator to make any clinical decision for treatment or diagnosis. The device permits the operator to take measurements from a patient, store this information for later transmission or transmit medical information to a Response Centre at the time of recording, where trained staff can make clinical assessments based on the information transmitted and advise the operator on the nature of the medical incident. A trained physician may use the Tempus 2000 Patient Monitor as a standalone diagnostic device.

The Tempus 2000 Patient Monitor is suitable for use on adults or children (over 10 years old and over 20kg in weight).

These indications have not changed as a result of the modification detailed in this submission.

4.2.1.2 Contraindications

The Tempus 2000 Patient Monitor is not intended to be used on extremely small or extremely large patients; this limit is set by the physical limits of the ECG harness.

The device is not intended to, and does not, sound alarms for physiological parameters. The device does not replace physician's care. The device is not intended for neonatal use. The device is not an apnoea monitor. The device is not intended to be a long-term monitor, it is only intended to be used in short, discrete incidents where the immediate health of the patient is in question.

The device is not intended to be used in strong magnetic or electro-magnetic fields which are generated for medical purposes e.g. MRI.

The ECG is not suitable to be used on patients with prosthetic limbs.

Note that these contra-indications have not changed as a result of the modification outlined in this submission.

4.3 Device Description

The Tempus 2000 Patient Monitor is a portable, multi-parameter patient monitor. The unit is housed in a plastic enclosure and comprises a large colour screen, a rechargeable battery and a wrist-mounted keypad which incorporates a digital camera.

The device can measure a patient's ECG (Electro Cardio Graph) using a 12-lead harness, non-invasive blood pressure, temperature (infra-red tympanic), respiration rate, end-tidal exhaled CO_2, pulse rate and SpO_2 (blood oxygen saturation).

The device collects the patient's physiological data and displays the data in numeric and graphical form to the operator and, remotely, to a Response Centre.

The operator interfaces with the device via 8 control buttons (with an additional button on the thermometer, a battery power level button and an on/off button on the front panel) and by graphical help-screens that are displayed in a logical sequence for ease of use. The helpscreens are displayed for all operations including operating the main medical functions, cleaning and repacking the unit and clearing basic errors that can be expected when using the system e.g. blood pressure hose occlusions or telecoms connection errors.

The device is fitted with a colour, digital video-stills camera for transmitting images of the patient to the Response Centre.

The Tempus 2000 Patient Monitor is designed to connect only to a PC which is configured with the Tempus Monitoring Station software.

Only very minor changes have been made to the design of the hardware and software (including the User interface) of the Tempus 2000. The Tempus Monitoring Station remains almost completely unchanged as a result of this modification.

4.4 Modification to the Existing Design

In the original design, the Tempus 2000 was connected to the Response Centre by means of two internal modems (connected to two separate satellite channels). This was because most existing applications required communication over such low bandwidth systems (2.4kbaud) that the voice and data signals had to be kept separate.

Subsequent advances in commercial satellite systems have resulted in an increase in available bandwidth; this has enabled RDT to provide a voice and data connection between the Tempus 2000 and the Response Centre using only a single channel. RDT has called this technology Digital Simultaneous Voice and Data (DSVD).

DSVD provides the User with a slightly easier connection process (one cable instead of two) and enables the device to be used in locations where there is only one available channel e.g. hotel rooms. All data is still transmitted in real time with the same exception of large files i.e. ECGs and videos, whose transmission time is at least as fast as before.

In addition, the ability to transmit the voice and data signals over a single channel has enabled RDT to incorporate an OEM cellular (GSM) phone into the Tempus 2000. This enables the Tempus 2000 to provide a combined voice and data connection over a wireless link as well as being able to use a conventional landline or a satellite terminal.

This modification requires only additional hardware within the Tempus 2000 and does not affect any of the existing hardware. Software remains largely the same except with regards to the connection of voice and data communication.

4.5 Predicate Devices

We consider the RDT Tempus 2000 to be substantially equivalent to the following predicate systems:

Manufacturer	Device Name	510(k) reference
RDT Ltd.	Tempus 2000 Patient Monitor (unmodified)	K010436
Ortivus AB	MobiMed Patient Monitor	K973318
Instromedix Inc.	Poseidon Cardiac Monitoring System	K964408

The modified Tempus 2000 is substantially equivalent to the original design as cleared to market by the FDA. The product provides all the same functions as were the case previously but with the alteration of providing voice and data over one channel instead of two and with the addition of being able to send this information over an integrated cell phone instead of only via a wired connection.

The use of a multiplexed voice and data signal is predicated on the Poseidon Cardiac Monitoring System by Instromedix Inc (K964408). It should be noted that this device was identified in the original Tempus 2000 510(k) as being a predicate device based on its similar application (being a telemedicine device intended to record BP, ECG, SpO2 etc in the home and transmit the data to a physician). This Poseidon device also provided a combined voice and data feature that gave the User a "press to speak" style voice link over the data link.

The use of a mobile (cell) phone for transmitting vital signs data is predicated on the MobiMed Patient Monitor manufactured by Ortivus AB. This is a telemedicine device which provides real-time vital signs monitoring (12 lead ECG, blood pressure, SpO2 etc.) and transmission of the data to a physician via an integrated OEM cell phone.

4.6 Testing

The revised Tempus 2000 design has been tested to determine that the device meets relevant international performance standards or guidelines e.g. IEC60601-1 and IEC60601-1-2.

Where the modification has not affected parts of the device covered by other performance standards e.g. AAMI EC13, EN60601-2-27, AAMI SP10, EN60601-2-30, EN865 and EN864, retesting has not been required as compliance remains unaffected by the change.

4.7 Software

The requirements of the FDA document *Guidance for the Content of Premarket Submissions for Software in Pre-Market Submissions* has been applied. In addition, the requirements of IEC60601-1-4 have been addressed.

4.8 User Trials

The modification to the User interface was not significant therefore formal trials on the device were not required. However, feedback on the design was obtained from Users during the design process.

4.9 Clinical Tests

The nature of the modification did not require clinical re-validation of the Tempus 2000. All medical aspects of the Tempus 2000 remain unchanged.

4.10 Bench Tests

The revised Tempus 2000 design has been tested to determine that:

- The device still meets existing design specification criteria.
- The existing performance specification in terms of measurement accuracy remains unchanged.
- The implementation of DSVD has had no impact on the transmission of voice or data.
- The operation of the integrated cell phone has had no impact on the measurement accuracy or performance of the device.

4.11 Conclusion

On the basis of these results and the above referenced testing, it is our determination that the device is safe, effective and performs as well as, or better than, the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully

5 September 2003

Chris Hannan
Product Validation Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2004

Remote Diagnostic Technologies Ltd
c/o Ms. Patricia L. Murphy
KEMA Medical
4377 County Line Road
Chalfont, PA 18914

Re: K033410
Trade Name: Tempus 2000 Patient Monitor, Model 00-0002
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: 74 DXH
Dated: February 19, 2004
Received: February 20, 2004

Dear Ms. Murphy:

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 (301) 594-4648. 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,

Donna R. Lachman

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: K033410

Device Name: Tempus 2000, Model 00-0002

Indications For Use:
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The ECG is not suitable to be used on patients with prosthetic limbs.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vechnel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033410