

510(k) Summary of Safety and Effectiveness

Submitter Information

Name: Remote Diagnostic Technologies Ltd

Address: The Old Coach House
The Avenue
Farleigh Wallop
Basingstoke RG25 2HT
United Kingdom

Phone Number: +44 1256 362 400

Fax Number: +44 1256 362 415

Contact Name: Chris Hannan

Date Prepared: 17 June 2011

Device Name

Common Name: Portable Patient Monitor

Proprietary Name: Tempus IC™ Patient Monitor, type 00-1001

Classification Name: Transmitters and Receivers, Electrocardiograph, Telephone

Device Description

The TempusIC™ is an advanced multi-parameter vital signs monitor designed for use in remote locations by trained non-expert users. It provides a wide range of features in a highly robust package, including integrated voice link and video camera.

The device remains unchanged from its previous/existing clearance with the exception that the device is now capable of receiving (wirelessly over a Bluetooth™ link) both tympanic temperature readings from a tympanic thermometer (cleared under K101264) and blood glucose data from the Entra Health Systems MyGlucoHealth glucometer (cleared under K081703).

Voice and data connections are made automatically via existing satellite or terrestrial communications systems.

The TempusIC™ is used in conjunction with TempusNET™ software, which provides a system for receiving real-time voice and vital signs data. The system

RDT Tempus IC Patient Monitor 510k Summary of Safety and Effectiveness

enables users to receive voice, vital signs data, and still video pictures from TempusIC™ devices located anywhere in the world.

The TempusNET™ system can be used by commercial response centre service providers or by individuals or organisations wishing to provide their own internal service

It also provides a synchronised user interface, and remote control of the TempusIC™.

TempusNET™ also supports a full patient records database.

Intended Use

The TempusIC™ Patient Monitor is intended to be used when a medical situation arises at a location remote from readily available medical expertise. Situations demanding use of the TempusIC™ Patient Monitor 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 TempusIC™ 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 TempusIC™ Patient Monitor to be used as either a stand-alone monitor or also connected to the TempusNET™ server system.

In the latter mode, the TempusIC™ Patient Monitor connects through TempusNET™ server system to a sister device, called the TempusNET™ monitoring station allowing the recorded data to be viewed, stored and manipulated by trained medical staff.

The TempusNET™ monitoring station comprises a normal, commercial grade PC which is dedicated to running the software that enables it to communicate with the TempusIC™ Patient Monitor. The TempusNET™ 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.

Indications for Use

Tempus IC is intended to aid with the diagnosis of a person presenting as unwell or sick when they are in a location remote from immediate medical assistance.

The device allows the User to take vital signs data from a patient and to transmit that data to medical professionals located at the response centre elsewhere.

Typical examples are remote land, sea or air locations.

RDT Tempus IC Patient Monitor 510k
Summary of Safety and Effectiveness

Tempus IC is intended primarily to be used by medically unqualified people who have received basic training in the use of the device. Medical expertise is provided through communication with the Response Centre which would be staffed by physicians who would advise the operator on the nature of the medical incident.

Tempus IC is intended to be used where a physician or other medically trained staff may or may not be present but where remote physician support is required.

Tempus IC measures non-invasive blood pressure, SpO₂, pulse rate, respiration rate and ETCO₂, 12 Lead ECG, tympanic temperature (via a wireless external module) and blood glucose (via a wireless external module).

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

Predicate Devices

The Tempus IC Patient Monitor is predicated on itself (as cleared to market without the ability to receive data from the thermometer or the MyGlucoHealth device). The clearance for the Tempus IC was granted under K082718.

The use of the tympanic thermometer is predicated on the clearance of the same thermometer with the Tempus IC Professional (granted under K101264).

The use of the MyGlucoHealth glucometer is predicated on the clearance of the same glucometer when it was cleared in its own right under K081703.

Operation of the device remains the same except with the addition of the two wireless peripherals, both of which have been cleared to market in the same form in previous applications which are substantially equivalent to their use with the Tempus IC.

Evidence of Conformity to Essential Principles

The device has been shown to conform to the essential principles for safety and performance defined in guidance prepared by the Global Harmonization Task Force Study Group1 (GHTF/SG1/N14R9:2005), with supporting evidence prepared in the summary technical documentation (STED) format recommended in final version of GHTF guidance (SG1/N011: 2008).

The design of this device utilises currently available (OEM) technology found in many legally marketed devices. In terms of measurement performance, the Tempus 2000 is effectively identical to the devices that incorporate the same OEM technology.

Testing

The Tempus IC Professional uses currently available (OEM) technology found in many legally marketed devices.

RDT Tempus IC Patient Monitor 510k
 Summary of Safety and Effectiveness

Area	Testing Performed
Comparative testing to predicates	Comparative testing has been performed to demonstrate that the performance of the device is equivalent to the predicates. This comprised benchmarking to confirm the MyGlucoHealth data was received reliably and accurately.
Software	The requirements of the FDA document <i>Guidance for the Content of Premarket Submissions for Software in Pre-Market Submissions</i> has been applied. In addition, the requirements of IEC62366 and IEC60601-1-4 have been addressed.
Bench testing	The glucometer has been bench tested to confirm that transmitted data is transmitted reliably and accurately.
Wireless range	The glucometer has been tested to confirm it operates reliably and accurately at its maximum stated range.
Wireless co-existence testing	The glucometer has been tested to confirm it operates reliably in the presence of other wireless fields as per the <u>FDA Guidance for Radio-Frequency Wireless Technology in Medical Devices</u> .
Usability	Usability has been address by the application of IEC62366

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

Chris Hannan
 Regulatory Affairs and Operations Manager



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

DEC 15 2011

Remote Diagnostic Technologies, Ltd
c/o Mr. William Sammons
Third Party reviewer, Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K113105

Trade/Device Name: Tempus IC Patient Monitor Model 00-1001 Regulation Number: 21
CFR 870.2300

Regulation Name: Cardiac Monitor

Regulatory Class: Class II (two)

Product Code: MWI

Dated: November 30, 2011

Received: December 1, 2011

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 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.

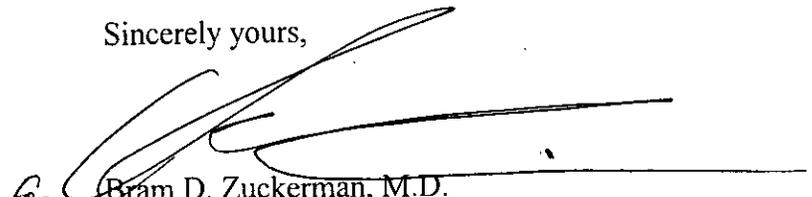
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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,


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

Enclosure

Statement of Indications for Use

510(k) Number (if known): Not known

Device Name: TempusIC™ Patient Monitor

Model number: 00-1001

Indications for Use:

Tempus IC is intended to aid with the diagnosis of a person presenting as unwell or sick when they are in a location remote from immediate medical assistance. The device allows the User to take vital signs data from a patient and to transmit that data to medical professionals located at the response centre elsewhere. Typical examples are remote land, sea or air locations.

Tempus IC is intended primarily to be used by medically unqualified people who have received basic training in the use of the device. Medical expertise is provided through communication with the Response Centre which would be staffed by physicians who would advise the operator on the nature of the medical incident.

Tempus IC is intended to be used where a physician or other medically trained staff may or may not be present but where remote physician support is required.

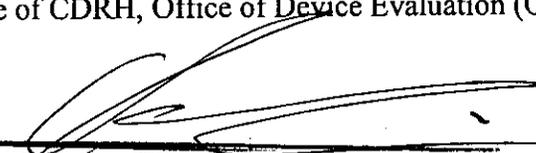
Tempus IC measures non-invasive blood pressure, SpO₂, pulse rate, respiration rate and ETCO₂, 12 Lead ECG, tympanic temperature (via a wireless external module) and blood glucose (via a wireless external module).

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

Prescription Use: YES AND/OR Over-The-Counter Use: NO
 (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 K 113105