



October 28, 2015

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

Remote Diagnostics Technologies Ltd
Chris Hannan
Director of Operations & Compliance
The Old Coach House, The Avenue, Farleigh Wallop
Basingstoke, Hampshire RG25 2HT UK

Re: K152124

Trade/Device Name: Tempus IC2
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: August 17, 2015
Received: August 18, 2015

Dear Chris Hannan:

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,


Bram D. Zuckerman -S

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

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Tempus IC2

Indications for Use:

“The Tempus IC2 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. The Tempus IC2 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.

The Tempus IC2 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 IC2 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).

The Tempus IC2 is suitable for use on adults or children (over 10 years old and over 20kg in weight).”

Description Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

510(k) Summary K152124

Submitter's Information

The submitter of this abbreviated pre-market notification is:

Name:	Remote Diagnostic Technologies Limited
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Contact Person:	Mr. Chris Hannan (Director of Operations & Compliance)
Date summary prepared:	17/07/2015

Device Identification

Device Trade Name:	Tempus IC2
Common Name:	Patient Monitor
Class:	II
Device Classification Name:	Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Product Code:	MWI
Regulation Number:	21 CFR 870.2300

Device Description

The Tempus IC2 device is a portable vital signs monitor that can measure 12 Lead ECG, non-invasive blood pressure, SpO2 and pulse rate, ETCO2 and respiration rate, temperature (via an unmodified third-party Bluetooth enabled tympanic thermometer) and blood glucose (via an unmodified third-party Bluetooth enabled glucometer). It also provides an integral camera, built-in third-party Bluetooth headset, touchscreen and membrane button controls, user removable lithium-ion battery and Ethernet, Wi-Fi and cellular phone communications. These are all the same features as provided by the Tempus IC.

The Tempus IC2 is intended primarily to be used as a telemedicine device for trained, non-healthcare practitioners in remote locations e.g. cabin crew on aircraft. It is designed to be easy to use and to transmit all data displayed to a healthcare practitioner in a different location. The healthcare professional receives the data on a PC installed with a programme called i2i. The device also transmits still or low-rate moving images (from the device to the i2i software) and also transmits voice communications through the use of an off-the-shelf Bluetooth headset which is connected to the back of the Tempus IC2. These descriptions are all the same as the Tempus IC.

The Tempus IC2 is provided in a bag which stores the device and the accessories and consumables needed to operate the device. This is the same as the Tempus IC which is also provided with a bag.

5.1 Indications for Use

The Tempus IC2 Indications for Use are the same as the predicate. The Indications for use are:

"The Tempus IC2 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

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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.

The Tempus IC2 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.

The Tempus IC2 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 IC2 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).

The Tempus IC2 is suitable for use on adults or children (over 10 years old and over 20kg in weight)."

Comparison with Cleared Device

RDT are moving their existing Tempus IC user interface and feature set on to their Tempus Pro hardware platform. The result of which will be a new/enhanced iteration of the existing Tempus IC product. This is a multi-parameter vital signs patient monitor (VSM) that provides a telemedicine platform for remote diagnosis. It will be based on the experience gained in the development of the current products (the Tempus IC and Tempus Pro), and includes the proprietary communications technology developed for the Tempus Pro but with a reduced feature set compared to what is offered with the Tempus Pro.

The intended use and indications for use, as well as the fundamental technology used in the Tempus IC2 device, remain essentially unchanged from the cleared Tempus IC.

Predicate Devices

The predicate devices are as follows:

Tempus IC2	Tempus IC (K113105)	Comparisons
Ease of Use		
<p>Control Interface User interface is provided by a touch screen, and simple graphically labelled buttons The user speaks with the physician via a wireless headset for hands-free operation All activities supported by full color helpscreens and graphics-based GUI. Requires as little as three hours training. Users are able to switch between multiple pre-configured communications options with only two button presses</p>	<p>Control Interface User interface is provided by a touch screen, jog wheel and simple graphically labelled buttons The user speaks with the physician via a wireless headset for hands-free operation All activities supported by full color helpscreens and graphics-based GUI Requires as little as three hours training Users are able to switch between multiple pre-configured communications options with only two button presses</p>	<p>The Tempus IC2 is same as Tempus IC but the jog wheel has not been included on the Tempus IC2</p>

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Tempus IC2	Tempus IC (K113105)	Comparisons
Pulse Oximeter		
<p>SpO2 Range: 1 -100% Accuracy (adults/child): no motion or low perfusion +/- 3 digits 70-100%, Perfusion Index range: 0.02% - 20% Signal strength indicator Uses comfortable, waterproof soft-tip sensor Pulse Rate Range: 25 – 239 BPM Accuracy (all ages): no motion ≤3 digits, motion ≤5 digits</p>	<p>SpO2₂ Range: 50 % - 100 % Accuracy: ±2 % at 70 % - 100 % Perfusion Index range: 1% - 20 % Signal strength indicator Employs patented SAC technology, Nellcor compatible Uses comfortable, waterproof soft-tip sensor Pulse Rate Range: 25 - 300 bpm Graphic display range 25-200 bpm Accuracy ±1bpm Resolution: 1bpm</p>	<p>Both devices use pulse oximetry to monitor blood oxygen saturation levels. Both devices use previously cleared OEM technology, the technology in the Tempus IC2 is equivalent to that used in the Tempus IC.</p> <p>The technology used in the Tempus IC2 remains substantially equivalent to that used in the Tempus IC based on its generally similar specification.</p>
Capnometer		
<p>Respiration Rate Range: 0 - 149 BPM Accuracy: 0-70 BPM ±1 BPM, 71-121 BPM ±2 BPM, 122-149 BPM ±3 BPM Sidestream ETCO2 Range: 0 – 150 mmHg Flow rate: 50 ml/min -7.5 + 15 ml/min Uses Oridion® Microstream® technology Accuracy: 0-38 mmHg ±2 mmHg, 39-150 mmHg</p>	<p>Respiration Rate Range 2-150 BPM Accuracy: ± 1BPM Sidestream ETCO2 Range: 0 – 150 mmHg Accuracy: ±2 % - ±10 % Delay time: <3 seconds</p>	<p>Tempus IC & Tempus IC2 both enable monitoring of respiration rate and ETCO2 via capnometry. And both utilise sidestream technology with similar specifications and features.</p>
Thermometer		
<p>Hand-held, Bluetooth® enabled infra-red tympanic thermometer Measurement range: 32°C - 43°C (target) (89.6°F – 109.4°F) Resolution: 0.1°C (0.1°F) Accuracy: ±0.2°C (36-39°C) ±0.4°C (<36°C & >39°C) [±0.4°F (96.8-102.2°F) ±0.5°F (<96.8°F & >102.2°F)] Bluetooth® communications range 0 – 10 m (0 – 32' 9")</p>	<p>Hand-held, Bluetooth® enabled infra-red tympanic thermometer Measurement range: 34°C - 42.2°C (target) (93.2°F - 108°F) Resolution: 0.1°C (0.2°F) Accuracy: ±0.2°C (36-39°C) ±0.3°C (<36°C & >39°C) [±0.36°F (96.8-102.2°F) ±0.54°F (<96.8°F & >102.2°F)] Display convertible to °F Bluetooth® communications range 0 – 10m (0 – 32' 9")</p>	<p>Both devices use a third party Bluetooth tympanic thermometer to measure temperature. Both devices use previously cleared OEM technology.</p> <p>The technology used in the Tempus IC2 remains substantially equivalent to that used in the Tempus IC based on its generally similar specification.</p>
Integral 3G/GSM Cell Phone		

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Tempus IC2	Tempus IC (K113105)	Comparisons
Able to connect over 2G GPRS networks (GSM 850, EGSM 900, DCS 1800 & PCS 1900) Able to connect over 3G GPRS networks (UMTS 850/Band V, UMTS 900/ Band VIII, UMTS 1900/ Band II & UMTS 2100/ Band I)	Able to connect over tri-band GPRS networks Operates over 900MHz, 1800MHz and 1900MHz bands	Device is the same as the predicate except it uses a quad band radio instead of a tri band radio.

In addition, reference is made to the cleared Tempus Pro patient monitor (K133988) which provides the hardware design (and consequently the burden of product verification testing) which the Tempus IC2 utilizes. The Tempus IC2 uses the majority of the Tempus Pro's hardware but does not make all the same performance claims and does not have the same Indications for Use or Intended Use and consequently a claim of substantial equivalence is not being made to the Tempus Pro.

Summary of Non-Clinical Testing

The non-clinical testing carried out is summarized in the following table:

Area	Testing Performed
Safety	Updated certification has been obtained to IEC 60601-1 3 rd ed by a qualified testing laboratory.
Ingress Protection	Ingress protection testing has been repeated in a qualified testing laboratory.
Comparative testing to predicates	Comparative testing has been performed using calibrated patient simulation equipment to demonstrate that the performance of the device is equivalent to the predicates.
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 IEC 62304 have been addressed.
Bench testing	The product has been bench tested to confirm that all data is transmitted reliably and accurately.

In each case the results of this testing confirmed that acceptance criteria defined by the relevant standard, or other appropriate reference document had been met.

With respect to usability, no additional user validation was considered necessary, as the Tempus IC2 is almost identical to the predicate Tempus Pro in terms of physical and interface features, including size and weight, user interface data layouts, button styles, menus, and layout of connectors, resulting the physical interaction with the device being unchanged.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket Notification, Remote Diagnostic Technologies Limited conclude that the Tempus IC2 Patient Monitor is substantially equivalent to the unmodified version of this device and other cleared devices used as predicates.