K082718

510(k) Summary of Safety and Effectiveness

OCT 10 2008

Submitter Information

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Date Prepared:	August 2008

Device Name

Common Name:	Portable Patient Monitor
Proprietary Name:	Tempus IC™ Patient Monitor
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.

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 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.

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

Predicate Devices

The TempusIC has been shown to be substantially equivalent to the Tempus 2000 Patient Monitor, which was the subject of two previous submissions (K033410 & ~~K101436~~).

K010436

Operation of the new device is essentially the same in terms of medical and communications function, but the TempusIC™ employs the latest hardware and software technology and materials to provide a more compact and robust unit. The TempusIC™ has been tested to the same standards as the predicate monitor.

All of the OEM medical modules and sensors used in the TempusIC™ have 510(k) clearance, and are used as intended by their manufacturers.

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).

Specifically, this evidence includes performance testing, software validation, electrical safety, electromagnetic compatibility, and risk analysis, where third party testing has been conducted, if appropriate.

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.

Software

The requirements of the FDA document Guidance for the Content of Premarket Submissions for Software contained in Medical Devices have been applied. In addition, the requirements of IEC 60601-1-4 have been addressed.

User Evaluations

User evaluations have been carried out with representative groups of professional, non-professional but trained, and untrained users, to confirm the ease-of-use design objective has been met.

Clinical Tests

Clinical tests have not been performed as all of the medical devices are currently cleared to market in applications that are individually substantially equivalent to the intended use of each medical parameter within the TempusIC™. Consequently, the use of clinical investigations to prove the efficacy of the measurement techniques was otherwise not required.

The functions and features of the TempusIC™ that are additional to the measurement of medical parameters have been tested and proven by bench and performance testing. In addition to bench testing of the various parameters, a conventional desat study was carried out to verify that the performance of the combined PCB and probe were within specification.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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OCT 10 2008

Remote Diagnostic Technologies Limited
c/o Mr. Kachi C. Enyinna
Intertek Testing Services NA, Inc.
2307 E Aurora Rd. Unit B7
Twinsburg, OH 44087

Re: K082718
Trade/Device Name: TempusIC™ Patient Monitor
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II
Product Codes: DXH
Dated: September 16, 2008
Received: September 17, 2008

Dear Mr. Enyinna:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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 K082718

Device Name: TempusIC™ Patient Monitor

Indications for Use:

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Prescription Use: YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: NO (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)

Jean B Zuckerman

(Division Sign-Off) 10/30/08

Division of Cardiovascular Devices

510(k) Number K082718