DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 6, 2017

Remote Diagnostic Technologies Ltd
James Hamlyn
Senior Regulatory Affairs Specialist
Pavilion C2, Ashwood Park, Ashwood Way
Basingstoke, RG23 8BG GB

Re: K170567
Trade/Device Name: Tempus Pro Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, MWI, CCK, DPS, DSB, DXN, DRT, IYO, ITX, MNR, DQA, FLL, DSK, DRG
Dated: May 25, 2017
Received: June 1, 2017

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170567

Device Name
Tempus Pro Patient Monitor

Indications for Use *(Describe)*
The Tempus Pro is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for: 3 & 5 Lead ECG monitoring; 12 Lead ECG recording with interpretation; real-time arrhythmia detection / alarming; QT measurement / alarming and ST measurements / alarming; impedance pneumography; non-invasive blood pressure (NIBP); end-tidal CO2 (ETCO2) and respiration rate; pulse oximetry (SpO2); contact temperature; and invasive pressure and extended pulse oximetry capability including; carboxy haemoglobin (SpCO), methaemoglobin (SpMet), total haemoglobin (SpHb) and total oxygen content (SpOC) measurements.

The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).

The device is indicated for adults, paediatrics and neonates.

The monitor can be used to display images from Interson 3.5 MHz General Purpose (GP) and 7.5 MHz Small Parts / Vascular (SR) USB ultrasound probes or a Karl Storz C-MAC S USB video laryngoscope. These optional accessories are to be used in accordance with their Indications For Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter's Information

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Contact Person:	James Hamlyn, Senior Regulatory Affairs Specialist
Date Summary Prepared:	May 25, 2017

Device Identification

Device Name:	Tempus Pro Patient Monitor
Common Name:	Patient Monitor
Classification:	II
Product Code:	MHX
Secondary Product Codes:	MWI, CCK, DPS, DSB, DXN, DRT, IYO, ITX, MNR, DQA, FLL, DSK, DRG
Regulation Number:	21 CFR 870.1025

Predicate Device(s)

Tempus Pro Patient Monitor - K133988 (including Tempus Pro approvals K130773, K134014 and K130773)

Device Description

The Tempus Pro is a multi-parameter vital signs monitor designed for use in pre-hospital care and remote clinical locations by trained healthcare professionals. It provides 3 & 5 lead ECG monitoring, 12 lead ECG recording, real-time arrhythmia detection & alarming, QT interval measurement & alarming, ST segment measurement & alarming, impedance respiration, pulse oximetry (including Masimo Rainbow® co-oximetry measurements i.e. SpOC, SpHb, SpMet, SpCO, PVI and PI), non-invasive blood pressure, sidestream capnometry, contact temperature, invasive pressure, and user configurable alarms. Third-party video laryngoscopes and ultrasound probes can be attached to the device.

In addition, it provides the ability to transmit all vital signs data via wired or wireless connections to a software system (called i2i) expected to be based in a facility far from the user e.g. a response centre facility. In addition to sending all vital signs, the system can also send pictures or video via an integrated camera, geographic position by an integrated GPS receiver, and voice via a wired or wireless headset.

The Tempus Pro was originally cleared under K130773 and was subsequently amended with new features under K133988 (extended SpO2, invasive pressure and 12 Lead ECG Interpretation), K134014 (ultrasound and laryngoscopy) and K133973 (ECG arrhythmia alarming). This 510(k) is to consolidate the Indications for Use statements that are different across the four 510(k)s.

Indications for Use

This submission proposes to consolidate the Indications for Use statements cleared under four separate 510k submissions to create a single statement that comprises all the elements from the four statements. The proposed Indications for Use are as follows:

The Tempus Pro is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for: 3 & 5 Lead ECG monitoring; 12 Lead ECG recording

with interpretation; real-time arrhythmia detection / alarming; QT measurement / alarming and ST measurements / alarming; impedance pneumography; non-invasive blood pressure (NIBP); end-tidal CO2 (ETCO2) and respiration rate; pulse oximetry (SpO2); contact temperature; and invasive pressure and extended pulse oximetry capability including; carboxy haemoglobin (SpCO), methaemoglobin (SpMet), total haemoglobin (SpHb) and total oxygen content (SpOC) measurements. The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere). The device is indicated for adults, paediatrics and neonates. The monitor can be used to display images from Interson 3.5 MHz General Purpose (GP) and 7.5 MHz Small Parts / Vascular (SR) USB ultrasound probes or a Karl Storz C-MAC S USB video laryngoscope. These optional accessories are to be used in accordance with their Indications for Use.

Comparison of Technological Characteristics

Tempus Pro, originally cleared under K130773, was amended by K133988 to include extended SpO2, invasive pressure and 12 Lead ECG Interpretation. Ultrasound and laryngoscopy and ECG arrhythmia alarming were cleared as additional feature sets to the Tempus Pro under K134014 and K133973 respectively. The sole purpose of this submission is to consolidate the Indications for Use statements that are different across the four 510(k)s for Tempus Pro. There is no technological difference between the predicate devices and subject device. The predicate devices and subject device have the same intended use; the same finished device specification; the same materials; the same mechanical, electrical and electronic components or assemblies; and the same accessories.

Substantial Equivalence – Non-Clinical Evidence

Non-clinical evidence was not necessary to demonstrate substantial equivalence. Software verification and validation testing has been included in the submission pursuant with FDA guidance document '*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'.*

Substantial Equivalence – Clinical Evidence

Clinical evidence was not necessary to demonstrate substantial equivalence.

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 Pro Patient Monitor with the changes described in this pre-market notification is as safe, as effective, and substantially equivalent to the predicate devices.