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

September 1, 2023

Re: K173768
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, FFL, DSK, DRG

Dear James Hamlyn:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 10, 2018. Specifically, FDA is updating this SE Letter to remove the secondary product code NSX as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter, please contact Aneesh Deoras, OHT2: Office of Cardiovascular Devices, 240-402-4363, Aneesh.Deoras@fda.hhs.gov.

Sincerely,

Aneesh S. Deoras -S

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

January 10, 2018

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

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Regulatory Class: Class II
Product Code: MHX, MWI, CCK, DPS, DSB, DXN, DRT, IYO, ITX, MNR, DQA, FFL, DSK, DRG, NSX
Dated: December 4, 2017
Received: December 11, 2017

Dear James Hamlyn:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173768

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; noninvasiveblood 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

06-1

510(k) SUMMARY

Submitter's Information

Name:	Remote Diagnostic Technologies Limited
Address:	Pavilion C2, Ashwood Park, Ashwood Way, Basingstoke, RG23 8BG, United Kingdom
Phone No:	+44 (0) 1256 362 400
Fax No:	+44 (0) 1256 362 415
Contact Person:	James Hamlyn, Senior Regulatory Affairs Specialist
Date Summary Prepared:	December 04, 2017

Device Identification

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

Predicate Device(s)

Tempus Pro Patient Monitor, K170567

Device Description

The Tempus Pro is a multi-parameter vital signs monitoring system 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 may also be connected to the device. In addition, it provides the ability to transmit all vital signs data via wired or wireless connections to a telemedicine software system 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.

This submission is to notify the FDA of our intent to market the Tempus Pro modified by the addition of an optional thermal printer, which enables the user of a Tempus Pro to print medical records on-demand. Additionally, compatible external devices may also print medical records on the Tempus Pro's optional thermal printer when paired to the Tempus Pro via a secure 1-to-1 data link called Tempus Data Link (TDL).

Indications for Use

No changes to the Indications for Use are proposed by this submission. The 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

The unmodified Tempus Pro currently enables a user to print medical records on an external printer connected via USB cable, and to also export patient records to ePCR, email, and USB flash drives. The modified Tempus Pro will continue to provide these features but with the addition of an optional printing function that will enable a user to print medical data directly from the device's thermal printer. Additionally, compatible external devices may also print records on the Tempus Pro's optional thermal printer when paired with the Tempus Pro via a secure 1-to-1 data link. All other functionality of the Tempus Pro monitor remains unchanged. No changes have been made to the device's indications for use, intended use, or fundamental scientific technology as a result of the modification that has prompted this submission.

Substantial Equivalence – Non-Clinical Evidence

The modifications to the device have been designed and assessed under design control processes compliant with FDA 21 CFR 820. Non-clinical testing has been performed to demonstrate that the safety and efficacy of the device remains substantially equivalent to its predicate.

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 Monitoring System with the changes described in this pre-market notification is as safe, as effective, and substantially equivalent to the predicate device.