September 18, 2020

Remote Diagnostic Technologies Limited
% Neha Hardiya
Regulatory Affairs Specialist
Philips North America LLC
22100 Bothell Everett Highway
Bothell, Washington 98021

Re: K201746
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, CCK, DPS, DQA, DRG, DRT, DSB, DSK, DXN, FLL, ITX, IYO, MNR, MWI, NSX
Dated: August 18, 2020
Received: August 19, 2020

Dear Neha Hardiya:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Jennifer Shih
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

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)*
K201746

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-, 4- and 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; carboxyhaemoglobin (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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5. 510(k) Summary

510(k) Summary

This 510(k) summary was prepared in accordance with the requirements of 21 CFR §807.92.

I. Contact Information

Submitter	
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
Correspondent	
Name	Neha Hardiya
Phone No.	425-908-2569
Email	neha.hardiya@philips.com
Date Prepared	August 18, 2020

II. Device Information

Trade Name	Tempus Pro Patient Monitor
Common Name	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
Classification	Class II (21 CFR 870.1025)
Product Code	MHX
Secondary Product Codes	CCK, DPS, DQA, DRG, DRT, DSB, DSK, DXN, FLL, ITX, IYO, MNR, MWI, NSX

III. Predicate Device Information

Primary Predicate Name	**Tempus Pro Patient Monitor**
510(k) Submission No.	K173768
Classification	Class II (21 CFR 870.1025)
Product Code	MHX
Secondary Product Codes	CCK, DPS, DQA, DRG, DRT, DSB, DSK, DXN, FLL, ITX, IYO, MNR, MWI, NSX
Secondary Predicate Name	**Infinity CentralStation Wide**
510(k) Submission No.	K151860
Classification	Class II (21 CFR 870.1025)
Product Code	MHX
Secondary Product Code	N/A

Prior Submission

This is an original submission. There has been no prior submission for the subject device.

IV. Device Description

The Tempus Pro Patient Monitor 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-Lead and 5-Lead ECG monitoring, 12-Lead ECG recording, real-time arrhythmia detection and alarming, QT interval measurement and alarming, ST segment measurement and 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 (called i2i) expected to be based in a facility far from the user e.g. a response center facility. As an alternative to i2i response center software, Tempus Pro Monitor also uses IntelliSpace Corsium, which is a web-based software platform for near real-time patient data transfer and two- way communication between healthcare professional. In addition to sending all vital signs, the system can also send pictures or video via an integrated camera, geographic positions by an integrated GPS receiver, and voice via a wired or wireless headset.

Additionally, Tempus Pro has an optional thermal printer, which enables the user to print medical records on-demand and allows other compatible external devices to print medical records as well using the optional thermal printer when paired to the Tempus Pro via a secure 1-to-1 data link called Tempus Data Link (TDL).

The Tempus Pro is provided to the user non-sterile. No accessories manufactured by RDT for use with Tempus Pro are provided sterile. The Tempus Pro does not come into direct or indirect contact with the patient. The Tempus Pro is compatible with 3rd party manufacturer accessories, for which patient contact and sterility requirements are determined by the 3rd party manufacturer.

Reason for Change

This submission is to notify the FDA of our intent to market the Tempus Pro modified by the addition of an optional off-the-shelf ECG interpretation algorithm, known as the Glasgow Algorithm. This off-the-shelf ECG algorithm will be available to the customer as an optional alternative to the ECG interpretation algorithm cleared under the previous 510(k) for Tempus Pro, known as the Louvain Algorithm.

The Glasgow ECG algorithm is being added to the Tempus Pro Monitor to accommodate customer preference. Users already familiar with use of the Glasgow ECG Algorithm on existing alternative devices have expressed interest in availability of Glasgow for the Tempus Pro.

If the user does not choose to purchase the new Glasgow Algorithm option via a software key, the Tempus Pro will continue to provide the 12-Lead ECG Interpretation using the

Louvain Algorithm originally cleared under 510(k) K133988. If the Glasgow Algorithm option is purchased, the Tempus Pro will output 12-lead ECG interpretations from Glasgow only (there is no option to use both 12-lead interpretation algorithms on the same device).

The Glasgow Algorithm is able to provide ECG interpretations for adult, pediatric, and neonate patients, when compared with the Louvain Algorithm that only provides the ECG interpretation for adults. However, the Tempus Pro already includes pediatrics and neonates in its labeled indications.

In addition to providing 12-lead ECG interpretations for adults, pediatric and neonate populations, Glasgow Algorithm is able to consider additional inputs for ECG analysis (e.g. age and sex), and is able provide interpretations under a greater breadth of conditions (e.g. waveforms that include pacemaker signals). However, this modification will not remove or change any other features available on the Tempus Pro device. Addition of the off-the-shelf Glasgow ECG interpretation algorithm will not change the indications for use or intended use for the Tempus Pro. As detailed in Section 13, algorithm validation data supports use of the Glasgow Algorithm in adults, pediatrics, and neonates.

Product Model Numbers

Table 5-1 below lists the Tempus Pro model numbers that are the subject of this 510(k).

Table 5-1. Tempus Pro Patient Monitor Model Numbers

Model Number	Description
00-1004-R	Standard configuration with invasive pressure (2 channels), $ETCO_2$ and contact temperature (1 or 2 channels).
00-1007-R	Standard configuration with invasive pressure (2 channels), $ETCO_2$, contact temperature (1 or 2 channels) and Bluetooth headset.
00-1024-R	Standard configuration with printer, $ETCO_2$ and contact temperature (1 or 2 channels).
00-1026-R	Standard configuration with printer, invasive pressure (2 channels), $ETCO_2$ and contact temperature (1 or 2 channels).

V. Intended Use

No changes to the Tempus Pro Intended Use are proposed by this submission.

The Tempus Pro is a portable vital sign 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.

RDT assumes that users of the product are clinically trained in how to take and interpret a patient's vital signs. The Tempus Pro is intended to be used by such clinically-trained personnel. Before attempting to work with the Tempus Pro, the user must read, understand,

and strictly observer all warnings, cautions and safety markings in the User/Operator Manual, other associated labeling and on the equipment.

Indications for Use

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

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-, 4- and 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; carboxyhaemoglobin (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.

VI. Comparison of Technological Characteristics with the Predicate Device

The intended use, indications for use, and technology used in the Tempus Pro device remains essentially unchanged by the addition of the Glasgow Algorithm as an optional alternative 12-Lead ECG interpretation algorithm. Table 5-2 below provides a summary of similarities and differences between the modified Tempus Pro that is the subject of this 510(k) and the primary predicate device Tempus Pro cleared per K173768. Table 5-2 (a) provides a summary of similarities between the subject device and the secondary predicate devices specific to 12-Lead ECG interpretation feature.

Table 5-2. Comparison of Technological Features with the Primary Predicate Device

Similarities	
Indications for Use	There is no change in the indications for use for the subject device in comparison to the primary predicate device. The subject device with alternative option for 12-Lead ECG interpretation algorithm is substantially equivalent to the primary predicate device.
Physical Dimensions	No modifications have been made to the physical dimensions of the subject device. It is substantially equivalent to the primary predicate device.

Similarities	
Physiological Parameters Measured	There is no change in the physiological parameters measured for the subject device. It is substantially equivalent to the primary predicate device.
Alarms	There are no changes to alarms. The subject device is substantially equivalent to the primary predicate device.
Display	There are no changes to the display. The subject device is substantially equivalent to the primary predicate device.
On-Screen Trends and Events	There are no changes to the on-screen trends and events. The subject device is substantially equivalent to the primary predicate device.
3-Lead and 5-Lead ECG Monitor	There are no changes to the 3-Lead and 5-Lead ECG monitoring. The subject device is substantially equivalent to the primary predicate device.
ECG Arrhythmia Monitoring	There are no changes to the ECG arrhythmia monitoring. The subject device is substantially equivalent to the primary predicate device.
Impedance Respiration	There are no changes to the impedance respiration specifications. The subject device is substantially equivalent to the primary predicate device.
Pulse Oximeter	There are no changes to the pulse oximeter specifications. The subject device is substantially equivalent to the primary predicate device.
Non-Invasive Blood Pressure	There are no changes to the non-invasive blood pressure specifications. The subject device is substantially equivalent to the primary predicate device.
Capnometer	There are no changes to the capnometer specifications. The subject device is substantially equivalent to the primary predicate device.
Contact Temperature	There are no changes to contact temperature specifications. The subject device is substantially equivalent to the primary predicate device.
Invasive Pressure	There are no changes to invasive pressure specifications. The subject device is substantially equivalent to the primary predicate device.
Ultrasound	There are no changes to the ultrasound specifications. The subject device is substantially equivalent to the primary predicate device.
Video Laryngoscope	There are no changes to the video laryngoscope. The subject device is substantially equivalent to the primary predicate device.
Communications and Wireless	There are no changes to communications or wireless specifications. The subject device is substantially equivalent to the primary predicate device.

Similarities	
Printing	There are no changes to the printer and the subject device is substantially equivalent to the primary predicate device.
EMC	Addition of the alternative 12-Lead ECG interpretation algorithm for the subject device does not impact EMC. The subject device is substantially equivalent to the primary predicate device.
Environmental Performance	There are no changes to the environmental performance specifications. The subject device is substantially equivalent to the primary predicate device
Differences	
12-Lead ECG Recorder	The Glasgow Algorithm is available as an alternative option for 12-Lead ECG interpretation in the subject device. While the Glasgow algorithm features additional input criteria for ECG interpretation, a more extensive ECG library, and is able to provide interpretations for adults, pediatrics, and neonates, it functions similar to the 12-Lead ECG algorithm (Louvain Algorithm) present in the primary predicate device and has the same intended use. Test data supports that this modification does not affect the substantial equivalence of the Tempus Pro device.
User Interface	With the addition of the Glasgow Algorithm to the subject device, the user interface has been updated to include: o Age/Sex warning message if no age/sex has been entered, which displays before entering the 12 lead view when Glasgow interpretation is installed. o Maintenance menu updated to include option for either US or UK English. **Service User Changes** o Glasgow 12-lead ECG waveform interpretation enabling option key under Maintenance and Settings option (Option key issued by RDT, for maintenance user personnel only) Test data supports that these modifications do not affect the safety or effectiveness of the Tempus Pro device.

Table 5-2 (b) below provides a summary of similarities between the modified Tempus Pro (subject device) and the Infinity CentralStation Wide (secondary predicate device). This summary is specific to the 12-Lead ECG interpretation feature available in both the devices.

Table 5-2 (a). Comparison of Technological Characteristics with Secondary Predicate Device (12-Lead ECG Interpretation)

Similarities	
Product Code and Device Classification	Tempus Pro and Infinity CentralStation Wide have the same primary product code MHX and are classified as Class II medical device (21CFR 870.1025).

Similarities	
Indications for Use	Both Tempus Pro and Infinity CentralStation Wide are used as patient monitoring systems and provide 12-Lead ECG interpretation. Per the assigned product code and device classification, both devices have the same common name: Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms).
12-Lead ECG Interpretation	Both Infinity CentralStation Wide and Tempus Pro uses Glasgow Algorithm for 12-Lead ECG interpretation and also considers similar input criteria for providing interpretation e.g. Patient Age and Gender, indicated to be used for adult and pediatric population.

Table 5-3 below provides the comparison for technological characteristics between the Louvain Algorithm cleared with the predicate Tempus Pro Monitor and the Glasgow Algorithm included with the proposed modified Tempus Pro.

Table 5-3. Comparison of Technological Characteristics between Louvain Algorithm and Glasgow Algorithm

Characteristic	**Louvain ECG Algorithm (Included with Predicate Device)**	**Glasgow ECG Algorithm (Included with Subject Device)**	**Comparison Summary**
Intended Use	12-Lead ECG Interpretation	12-Lead ECG Interpretation	Intended use is identical.
Target Population (Specific to 12-Lead ECG Interpretation)	Used with Tempus Pro Monitor for ECG interpretation available for patients aged 18 years and over.	Used with Tempus Pro Monitor for ECG interpretation available for patients including adults, neonate, and pediatric.	Glasgow Algorithm provides interpretation for adults, neonates, and pediatric population as compared to the Louvain Algorithm that only provides interpretation for adult patients. Note that Tempus Pro Monitor is currently cleared for adults, pediatrics, and neonates in its labeled indications.

Characteristic	Louvain ECG Algorithm (Included with Predicate Device)	Glasgow ECG Algorithm (Included with Subject Device)	Comparison Summary
Method of Operation	The Louvain library software runs on the Tempus Pro at the end of recoding a 12-Lead ECG. Measurement and interpretation data indicated as statements on the monitor are then incorporated into the recorded ECG. See Figure 10-5. These measurements and interpretation data can be displayed on the Tempus Pro, printed, exported or transferred over the telemedicine communication links.	The Glasgow library software runs on the Tempus Pro at the end of recording a 12-lead ECG. Measurements and interpretation data indicated as statements on the monitor are then incorporated into the recorded ECG. See Figure 10-6. These measurements and interpretation data can be displayed on the Tempus Pro, printed, exported or transferred over the telemedicine communication links.	Method of operation is identical.
Interpretation and Review	ECG data recorded in the SCP files is interpreted by AnalyzeSCP.exe and statement codes are displayed as sub-headings Rhythm Statement and Morphology Statement. See Figure 10-5.	ECG data recorded in the SCP files is interpreted by Glasgow and the statement codes for rhythm statement and morphology statement are displayed without any sub-headings. See Figure 10-6.	Interpretation data provided by Glasgow and Louvain Algorithm is similar. Louvain displays data with sub-headings and Glasgow displays date without sub-heading on the monitor.
Data Input Criteria	SCP files will be passed to AnalyzeSCP.exe only when the heart rate is greater than or equal to	Glasgow library is not limited by any heart rate restrictions and can	Glasgow Algorithm considers a wider range of input criteria for 12-Lead ECG interpretation as

Characteristic	Louvain ECG Algorithm (Included with Predicate Device)	Glasgow ECG Algorithm (Included with Subject Device)	Comparison Summary
	30 Bpm and less than or equal to 160 Bpm. Louvain library cannot analyze recorded ECG that contains pacemaker signals. Louvain library cannot detect recorded ECGs that contain periods of lead-off or invalid data. Patient age and gender is not a required input criteria.	analyze any recorded ECG heart rate. Glasgow library can analyze recorded ECG that contains pacemaker signals. The Glasgow library can detect recorded ECGs that contain periods of lead-off or invalid data, provided there is at least one V-lead present throughout the recording. Patient age and gender is required input criteria.	compared to Louvain Algorithm.
Data Output Criteria	Louvain can output ST20 and ST60 measurements (ST elevation at the J-point +20ms and +60ms).	Glasgow provides ST Elevation Myocardial infarction (STEMI) detection and classification. ST20 and ST60 measurements (ST elevation at the J-point +20ms and +60ms) would primarily be used by the clinical user to assist in the diagnosis of ST Elevation Myocardial infarction (STEMI) and other related conditions. The Glasgow algorithm provides STEMI detection and classification, therefore the omission of reported individual ST20 and ST60 lead measurements is not considered a loss of functionality or performance.	Both algorithms provide analysis features relative to diagnosis of ST Elevation Myocardial infarction (STEMI). The Glasgow algorithm provides direct STEMI detection and classification, while Louvain outputs ST20 and ST60 elevation measurements.

VII. Performance Data

Software Verification and Validation

Software verification and validation testing were conducted and documentation was provided as recommended by *FDA's Guidance for Industry and FDA Staff-Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (2005).* The Software Level of Concern for Tempus Pro Monitor was determined to be **Major**, since failure or latent flaw in the software could cause harm to the patient indirectly due to a failure or fault in the presentation of data, resulting in delay in treatment or diagnosis.

Table 5-4. Summary of Software Testing

Device Change	Summary of Verification/Validation Methods	Acceptance Criteria	Summary of Results
Addition of New 12-Lead ECG Algorithm (Glasgow Algorithm)	Glasgow algorithm was tested using test vector files provided by Glasgow University to exercise the ECG interpretation library on the Tempus Pro. The Tempus Pro output interpretations were compared with known interpretations for the input vectors to show that there were no differences between the known reference interpretations and the output produced after the Glasgow Algorithm had been integrated into the Tempus Pro.	All interpretations output from the Glasgow library run on Tempus Pro shall match the known reference interpretations.	**PASS** A total of 612 known vectors were used for comparison with interpretations from Tempus Pro. The results obtained were consistent with the results expected by Glasgow University.
	Tested function of the Glasgow interpretation software under different conditions. This included testing consistency of the Glasgow interpretation between the Tempus Pro user interface, Tempus Pro pdf report, thermal printer output, display on Intellispace Corsium ECG tab and Intellispace Corsium pdf report.	The interpretation statement shall be printed in bulleted format without any heading and shall be identical between the Tempus display, the thermal printer output, pdf report, Intellispace Corsium review display and Intellispace Corsium pdf. Additional criteria	**PASS** Glasgow library was tested for reliability and consistency. Interpretation results were found to be identical on Tempus Pro, Corsium, thermal printer output, PDF reports and Corsium PDF reports.

Device Change	Summary of Verification/Validation Methods	Acceptance Criteria	Summary of Results
		as detailed in test protocol/report.	
	Tempus Pro Software Changes Testing. The new features added to the Tempus Pro software were validated, including features related to the addition of the Glasgow Algorithm.	All software features tested shall output the expected result per the protocol and associated software specification.	**PASS** All software features tested performed as specified in the protocol and associated SW specification document.
	Integration Acceptance Test Protocol (IATP). This protocol describes a set of testing (validation) for the integrated Tempus Pro software; it was constructed to exercise all the main features of the software. This protocol was used as final validation and does not replace the detailed Acceptance Test Protocols (ATPs) exercised by the software development test team. The protocol included tests of the stand-alone Tempus Pro and the system including the Data Centre and i2i (Response Centre).	Outputs shall meet the acceptance criteria defined in IATP protocol.	**PASS** All outputs met the acceptance criteria defined in the IATP protocol.
	Software unit and system testing performed by third party software developer.	Outputs of software and unit test shall meet the criteria defined in the relevant software specifications.	**PASS** All system and unit testing met the criteria per the relevant software specifications.

Electrical Testing

The modification to the device was designed and assessed under design control processes compliant with FDA 21 CFR §820. Non-clinical testing was performed to demonstrate that the device is substantially equivalent to its predicate. The non-clinical testing performed to assess the addition of the Glasgow Algorithm included compliance with the following:

- IEC 60601-2-25: 2011, Medical Electrical Equipment - Part 2-25: Particular Requirements for The Basic Safety and Essential Performance of Electrocardiographs (Clause 201.12.1.101)

Test results confirmed that the acceptance criteria defined by IEC 60601-2-25:2011 was met.

Clinical Testing

No clinical testing was performed. Clinical reference data, in the form of recorded ECG databases, were used for initial validation of the Glasgow Algorithm and integration testing specific to use with Tempus Pro.

Performance Testing not Impacted by Device Modification

As the addition of the Glasgow Algorithm is a software change only, it does not affect any Tempus Pro accessories, including any associated sterilization, biocompatibility, or shelf life testing. Because the user interface remains largely identical, with only an added age/sex warning message and option for either UK or US English interpretation output, it was determined that repeating usability and human factors testing was not necessary.

VIII. Conclusions

The results of the substantial equivalence assessment, taken together with software and electrical testing, demonstrate that the Tempus Pro Patient Monitor with the modifications described in this premarket notification does not raise different questions of substantial equivalence when compared to the predicate devices. The device performs as intended and has performance characteristics that are substantially equivalent to the Tempus Pro Patient Monitor predicate device cleared per K173768 and Infinity CentralStation Wide specific to 12-Lead ECG interpretation cleared per K151860.