February 3, 2022

Elastic Care Incorporated
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K211822
Trade/Device Name: LifePath Remote Patient Monitoring Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: January 4, 2022
Received: January 5, 2022

Dear Prithul Bom:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211822

Device Name
LifePath Remote Patient Monitoring Platform

Indications for Use *(Describe)*
The LifePath Remote Patient Monitoring Platform connects with compatible physiological measurement devices (blood pressure meters, pulse oximeters, thermometers, glucometers) to collect vital sign using a Patient App and securely transmit them, unaltered, to LifePath servers. The LifePath Platform is intended to be used at home or in healthcare-related environments such as long-term care facilities or clinics, nursing homes and hospitals. The LifePath Remote Patient Monitoring Platform serves as Software as a Medical Device and can be used only with specific FDA cleared third-party measurement devices.

The LifePath Remote Patient Monitoring Platform securely stores the collected information on LifePath servers and make it available for viewing by remotely located clinicians using a Clinician App installed on their smartphones. The clinician can analyze the data, prescribe medications or contact the patient if needed. Clinicians can set thresholds individually for each patient; notifications are sent to the clinician for threshold breaches.

The LifePath Platform does not interpret, make diagnoses or serve as a substitute for medical care. It is not intended to provide real time data.

The LifePath Platform is contraindicated for use in high-acuity environments, such as the ICU or operating rooms, and is not intended for use on acutely or critically ill patients or those requiring time-critical or emergency intervention.
It is intended for patients who are willing and capable of managing its use or where its operations can be performed by a caregiver. Clinical judgment and experience of a Clinician are required to check and interpret the information delivered.

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.

510(k) Summary

[As per the requirements of 21 CFR Part 807.92]

1 SUBMITTER IDENTIFICATION

Company name:	**ELASTIC CARE INCORPORATED**
Company Address:	95 Apple Creek Blvd., Markham, Ontario L3R 1C7 Canada
Phone:	(416)-704-5141
Fax:	(416)-214-6238
Contact Person:	Ashok Kalle
Contact Email:	ashok.kalle@pathcom.com
Date Prepared:	17 May 2021

2 SUBMITTER CORRESPONDENT

Contact Person:	Prithul Bom
Address:	Regulatory Technology Services, 1000 Westgate Drive, Suite #510k Saint Paul, MN 55114
Phone:	612-963-0379
Contact Email:	prithul.bom@rts3pro.com

3 DEVICE IDENTIFICATION

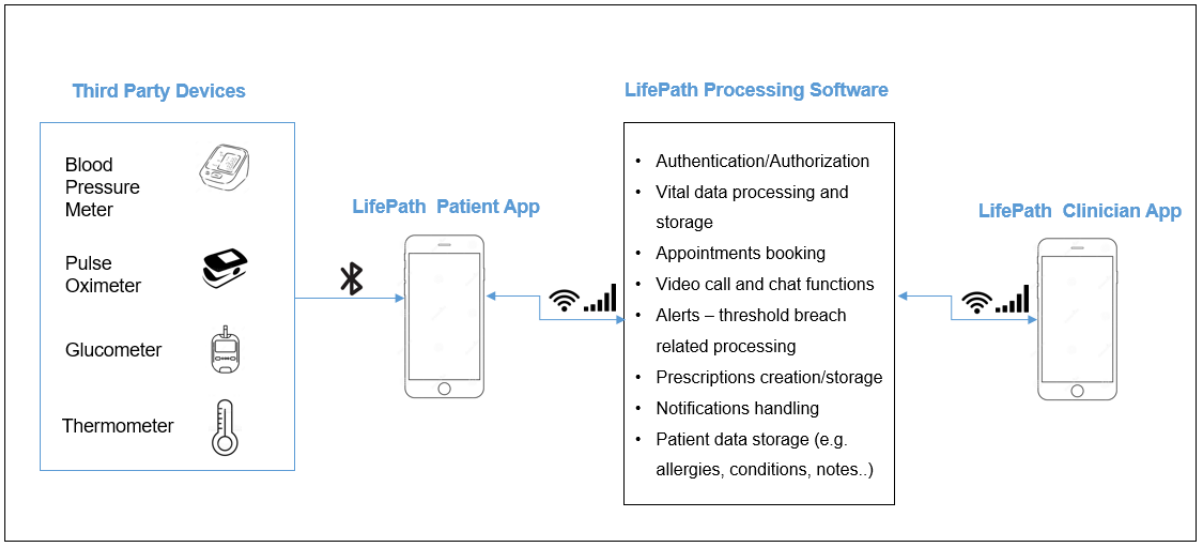
Trade Name:	LifePath Remote Patient Monitoring Platform
Common Name:	LifePath RPM Platform
Device Class:	II
Classification Regulation Number: 870.2910	
Classification Name:	Radiofrequency physiological signal transmitter and receiver
Product Code:	DRG
Classification Panel:	Cardiovascular

4 LEGALLY MARKETED PREDICATE DEVICE(S)

Predicate Device: Comarch e-Care Platform, K181248

5 DEVICE DESCRIPTION

The LifePath Remote Patient Monitoring Platform (the "LifePath RPM Platform") is a software application. It is used in conjunction only with FDA cleared Commercial, Off-The-Shelf (COTS) Third-Party Medical Devices (TPDs). These TPDs are with Bluetooth functionality to collect, aggregate, and present, without modification, vital signs and symptoms required by clinicians to assess a patient's health. The device is intended for patients who have non-critical conditions and are located either in their own homes or in professional healthcare facilities such as hospitals, skilled nursing facilities, nursing homes, or long-term care facilities. The LifePath RPM Platform constitutes a telemedicine system for remote monitoring of patients with the connected Clinician. Both the Patient App and Clinician App are accessed via authentication using a one-time security code by the respective users.



The LifePath Patient App connects through a short-range radio system using Bluetooth to FDA 510(k) cleared devices (listed in Table 1 below) to measure physiological parameters of adult patients and securely transmit unmodified data to the LifePath Processing Software residing on the LifePath Server (or central server) for storage, formatting, remote display, and download. The information is available for secure viewing by remotely-located healthcare professionals (eg.

Clinicians). The data may be retrieved and viewed via the Clinician App and Patient App on smartphones through internet access using local Wi-Fi 802.11 or a 3G/4G/LTE cellular network. By using the Clinician App a Clinician can view the vital signs of the connected patient, analyze the data, and prescribe medications. Clinicians will also be able to set thresholds for each patient such that notifications will be sent to the Clinician in the event of any threshold breach. The LifePath RPM Platform will be prescribed by the Clinician to the patient as per the need to remotely monitor the patient. The patient, using the Patient App, can book appointments with the Clinician. The Patient App also has the provision for the patient to respond to the Clinician's questions on their prior health conditions, medical conditions, any allergic conditions, etc., that will enable Clinicians to get a clear medical status of the patient. The patient and the Clinician can interact through chats and video calls using their respective apps.

The LifePath RPM Platform is not intended for use in high-acuity environments, such as the ICU or operating rooms, and is not intended for use on acutely or critically ill patients or those requiring time-critical or emergency intervention.

5.1 Physiological Parameters from Third-Party Medical Devices

The LifePath RPM Platform gathers physiological parameter readings transmitted by Third-Party Medical Devices ("TPDs") using Bluetooth LE. These third-party bedside or mobile devices shall each have individually received FDA 510k clearance and the LifePath RPM Platform will have been configured to receive physiological parameter readings from them by integrating the device-specific software(s). Physiological vital signs and parameters measured include the following medical devices:

- Pulse rate from a Pulse Oximeter
- Peripheral oxygen saturation (SpO2) from a Pulse Oximeter
- Skin temperature from a digital thermometer
- Systolic and diastolic blood pressure from a non-invasive BP Monitor
- Blood sugar (glucose) from a Glucometer

The following table lists the FDA 510k cleared third-party medical devices from which the LifePath RPM Platform receives physiological parameters:

Table 1

Physiological Parameters	**Device**	**Manufacturer**	**Model**	**510 (k) number**	**Date cleared (MM/DD/YYYY)**
Pulse rate, Peripheral oxygen saturation (SpO2)	Pulse Oximeter	Shanghai Berry Electronic Tech Co., Ltd	BMC1000C	K172141	04/04/2018
Skin temperature	Clinical Electronic Thermometer	Shenzhen Jumper Medical Equipment Co., Ltd.	JPD-FR400	K172795	03/14/2018
Blood sugar (glucose)	Blood Glucose Monitoring System	Tyson Bio	HT100B	K170079	10/06/2017
		All Medicus Co., Ltd.	ABM-513S	K170241	10/13/2017
Systolic and diastolic blood pressure	Non-invasive Blood Pressure Measurement System	Shenzhen Belter Health Measurement And Analysis TE	ePA-46B4	K134029	07/25/2014

5.2 LifePath RPM Platform – MAJOR COMPONENTS

The LifePath RPM Platform consists of the following:

a) The **LifePath Patient Application** ("**Patient App**"). This is downloaded and installed on a mobile phone which is in the proximity of the person whose vital signs are being monitored. The patient may seek assistance from a caregiver in operating the App and collecting vital signs.

The Patient App receives the vital signs data from the third-party medical devices over Bluetooth LE and transmits them, encrypted and unmodified, over the Internet to the "LifePath Processing Software" installed on a secure, remote central server. The Patient App must be turned on and be available within Bluetooth range of the third-party devices at the location of the individual(s) whose vital signs and parameters are being monitored.

b) The **LifePath Processing Software** ("**Processing Software**") receives, stores, formats, and makes the vital signs information accessible for viewing by Clinicians. Notifications will be sent to the Clinician for any threshold breaches

set by the Clinician. The Processing Software resides in the central server (LifePath Server).

c) A **LifePath Clinician Application** ("**Clinician App**"). This is downloaded and installed on a mobile phone used by the Clinician who is monitoring the patient. The Clinician App is an interface to observe physiological parameters, to view and respond to alerts, and to perform other administrative functions that do not involve vital signs.

Elastic Care onboards healthcare professionals such as Clinicians by background verification of their credentials. They are required to have skills to interpret physiological parameters and vital signs.

5.3 LifePath RPM Platform Feature Summary

The LifePath RPM Platform includes the following features and functions:

a. Creation of a master patient record on the central server which contains patient information.
b. Setting of individual thresholds by a Clinician for each vital sign or parameter, and for sending alerts to the Clinician when these thresholds are crossed.
c. The ability for the reviewing clinician to add annotations and notes to the patients' record.
d. Reminders and alerts for patients and Clinicians related to medical and non-medical activities.
e. Scheduling of appointments by the patient with the Clinician using the Patient App.
f. Issue of secure electronic prescriptions by the supervising Clinician from the Clinician App in conformance to legal requirements.
g. Communications between the Clinician and the patient via video and chat.
h. The ability for the clinicians and patients to manually enter patients' vital signs and symptoms into the patient records using the Patient App.
i. Storage and display of historical patient vital signs.
j. Maintenance of records of consultation for Clinician billing and audit.

5.4 Mode of Operation

The LifePath RPM Platform is a software application constituting a telemedicine system for remote monitoring of patients with the connected Clinician. It is used in

combination with FDA cleared TPDs with Bluetooth functionality to collect, aggregate, and present, without modification, vital signs and symptoms required by clinicians to assess a patient's health. The Patient's vital sign data can be viewed by the Clinician using the Clinician App over cellular or Wi-Fi networks to analyze and prescribe medications or provide medical advice. Clinicians can also set thresholds for individual patients and receive notifications for any breach. The LifePath RPM Platform also provides the capability for the patient to book consultations with the Clinician and interact using either chat or video call facility. All patients shall have non-critical conditions and shall not require in-person emergency medical care.

The proposed conditions for use of the LifePath RPM Platform are listed below.

5.4.1 Hardware hosts for Patient and Clinician Applications:

a. Android (version 8 and above).
b. Smartphones with screen sizes equal to, or greater than, 5.7 inches diagonally.
c. Processor: 2 core - 1.2 GHz or faster processor.
d. RAM: Minimum 2 GB or more.
e. ROM: Minimum 2 GB or more.
f. Network Bandwidth: More than 1 MBPS (Internet access using local Wi-Fi 802.11 or 3G/4G/LTE cellular.
g. Bluetooth: version 2.0 and higher and operating frequency of 2.4 GHz.

The LifePath RPM Platform ensures the security of transmitted data via encryption in compliance with HIPAA requirements.

6 INDICATION FOR USE

The LifePath Remote Patient Monitoring Platform connects with compatible physiological measurement devices (blood pressure meters, pulse oximeters, thermometers, glucometers) to collect vital sign using a Patient App and securely transmit them, unaltered, to LifePath servers. The LifePath Platform is intended to be used at home or in healthcare-related environments such as long-term care facilities or clinics, nursing homes and hospitals. The LifePath Remote Patient Monitoring Platform serves as Software as a Medical Device and can be used only with specific FDA cleared third-party measurement devices.

The LifePath Remote Patient Monitoring Platform securely stores the collected information on LifePath servers and make it available for viewing by remotely located clinicians using a Clinician App installed on their smartphones. The clinician can analyze the data, prescribe medications or contact the patient if needed. Clinicians can set thresholds individually for

each patient; notifications are sent to the clinician for threshold breaches.

The LifePath Platform does not interpret, make diagnoses or serve as a substitute for medical care. It is not intended to provide real time data.

The LifePath Platform is contraindicated for use in high-acuity environments, such as the ICU or operating rooms, and is not intended for use on acutely or critically ill patients or those requiring time-critical or emergency intervention.

It is intended for patients who are willing and capable of managing its use or where its operations can be performed by a caregiver. Clinical judgment and experience of a Clinician are required to check and interpret the information delivered.

7 COMPARISON OF TECHNOLOGICAL

7.1 Characteristics with Legally Marketed Predicate Device

Table 2: The table below describes the similarities and differences with respect to the intended use, principle of operation, and technological characteristics between the subject device and the predicate device.

Table 2

Sl #	Feature	Predicate Device Comarch E-Care Platform (K181248)	Subject Device Lifepath Remote Patient Monitoring Platform (Pending)
	Device Classification	II	II
	Product Code	DRG	DRG
	Regulation Number	870.2910	870.2910
1.	**Indications for Use**	The Comarch e-Care Platform is intended to connect with physiological measurement devices (weight scales, blood pressure meters, pulse oximeters, peak flow meters, thermometers, spirometers, glucometers) intended to use at home and send the measurement results to central server. Comarch	The LifePath Remote Patient Monitoring Platform connects with compatible physiological measurement devices to collect vital sign measurements intended to be used at home or healthcare-related environments and securely transmit them unaltered to the LifePath server. LifePath Remote Patient Monitoring Platform

		e-Care Platform serves as Software as a Medical Device and can be used only with FDA cleared measurement devices. Comarch e-Care Platform displays the collected measurements on the Web application and securely stores them in a database server, where the caregiver can view the results, analyze them, leave comments and contact patient if necessary. Caregivers are able to set thresholds individually for each patient. Measurement results sent to e-Care Platform from connected devices are analyzed and if result is beyond the threshold, caregiver gets the notification. The Comarch e-Care Platform is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real-time data. It is made available to patients when time-critical care is not required. The Comarch e-Care Platform is contraindicated for patients requiring direct - medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.	serves as Software as a Medical Device and can be used only with specific FDA cleared third-party measurement devices. The LifePath server securely stores the collected information and makes it available for viewing to remotely located clinicians using the Clinician App installed on their smartphones. The clinician can analyze the data, prescribe medications or contact the patient if needed. Clinicians can set thresholds individually for each patient and for any threshold breach, notification is sent to the clinician. The LifePath RPM Platform does not interpret, make diagnoses nor serve as a substitute for medical care. The LifePath RPM Platform is contraindicated for use in high-acuity environments, such as the ICU or operating rooms, and is not intended for use on acutely or critically ill patients or those requiring time-critical or emergency intervention. It is intended for patients who are willing and capable of managing its use or can be assisted by a caregiver. Clinical judgment and experience by a Clinician are required to check and interpret the information delivered.
2.	**Intended use**	Telemedicine system	Telemedicine system

3.	**Intended users**	Home users and healthcare providers.	Home users and healthcare providers.
4.	**Site of Use**	Healthcare related environment or home	Healthcare-related environment or home
5.	**Patient population**	The medical device is intended for adult users.	The medical device is intended for adult users.
6.	**OTC and/or Rx**	Rx	Rx
7.	**Contraindication**	The Comarch e-Care Platform is contraindicated for patients requiring direct – medical supervision or emergency intervention.	The LifePath RPM Platform is not intended for use in high-acuity environments, such as the ICU or operating rooms, and is not intended for use on acutely or critically ill patients or those requiring time-critical or emergency intervention.
8.	**Data collection software**	Comarch e-Care software application, Comarch SMA software application	LifePath proprietary server software, LifePath Patient Software Application
9.	**Data collection software functionality**	Transmit data from measuring devices and store data in a central database.	Collect data from measuring devices and transmit them to a central server (LifePath Server).
10.	**Communication method of hub with central server**	Any Internet access method with Ethernet or Wi-Fi 802.11 b/g/n interface or 3G/4G network.	Internet access using local Wi-Fi 802.11 or 3G/4G/LTE cellular network.
11.	**Types of measuring devices which can be interfaced to receiver hub**	Medical devices designed for home use: glucose meters weight scales, blood pressure meters, pulse oximeters, peak flow meters, thermometers, spirometers.	Medical Devices designed for home use: FDA 510K cleared glucometers, pulse oximeters, blood pressure meters, and thermometers
12.	**Measuring device software**	Measuring device software unchanged	Measuring device software unchanged
13.	**Communication with**	Short-range radio system using Bluetooth	Short-range radio system using Bluetooth

	measuring devices		
14.	**Method implemented for collecting data from measuring devices**	Bluetooth v2.0 and Bluetooth v4.0	Bluetooth v2.0 and higher
15.	**Measuring devices communication frequency**	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz
16.	**Power source**	Wall power plug (120 VAC/50-60)	Wall power plug (120V AC 50-60) to charge mobile devices and laptops.
17.	**Display**	On devices and hub, and monitors connected to the central server	On third party medical devices, on the Patient App and on the Clinician App.
18.	**Communication with patients**	Visual reading and feedback on hub's screen. Phone call and email messages from caregiver	Visual reading and feedback on Patient App (mobile device), chats, email messages, video calls, and phone calls from/to caregiver.
19.	**Use of thresholds /algorithms for determining how thresholds are set and changed**	Thresholds are set by Healthcare professionals in server software and sent to the hub. Hub performs the analysis and sends it back with results to server software	Individual patient thresholds are set by the Clinician in LifePath Processing software residing in the server (LifePath Server). The server software compares data received against the pre-set thresholds.

The subject and the predicate devices have the same intended use which is to connect remotely located clinicians with patients located at home to receive care/consultations based on collected vital sign measurements. The subject device can be used in healthcare-related environments or at home in a manner similar to the predicate device. Like the predicate device, the subject device is intended for adult users and is to be used upon the prescription and instructions of a registered clinician.

The subject device, like the predicate, connects to FDA cleared third-party measurement devices via a short-range radio system using Bluetooth communications operating at standard 2.4 GHz frequency, without changing the measuring devices' software. The data collection software in both the devices has a similar function, which is to collect data from measuring devices and transmit them to a central server using the same technology i.e., over the Internet either using a Wi-Fi connection or a 3G/4G or LTE cellular network.

The collected information is securely stored in the server by both devices, however, the subject device displays them in the Clinician App (through a mobile device) and the predicate device does so on the web application (through their hub). In both devices, caregivers/clinicians can analyze the displayed data and contact patients if needed. As the predicate allows the caregivers to leave comments, the subject device allows the clinicians to also prescribe medications based on the collected information and their experience. Like the predicate device, clinicians in the subject device can set thresholds individually for each patient but the algorithm used to analyze the threshold breaches in the subject device resides in the central server software, unlike the predicate. Essentially, in both the devices, the analysis is done by software, but residing in a hub and a server. The subject device facilitates a similar communication between patients and clinicians as the predicate device and also, provides chat and video calls functionalities.

Though both the devices have similar contraindications for patients, the subject device has defined certain environments and patients who are not recommended to use this device. Neither the subject device nor the predicate device is interpretive, makes diagnoses, or serves as a substitute for medical devices. Both devices are recommended for patients who are willing and capable of managing their use.

8 NON-CLINICAL PERFORMANCE DATA

The LifePath Remote Patient Monitoring Platform was verified and validated using a robust and detailed software verification and validation plan. It was based on the FDA guidance document: General Principles of Software Validation; Final Guidance for Industry and FDA Staff.

All executable code and functionality were tested against design specifications, including accessibility, communication, and business components, data storage, processing, and multi-level security, to ensure that each component of the software performs as intended. Tests executed were documented as recommended by the FDA Guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Risk Analysis was performed as recommended by ISO 14971:2007 *Medical devices - Application of Risk Management to Medical Devices* and risk controls were implemented to mitigate all identified hazards through suitable modifications to software functionality, user interfaces, documentation, labeling, user instructions, and SOPs. This ensured that the Elastic Care LifePath Remote Patient Monitoring Platform met all design requirements and risk controls were in place for all identified risks.

An extensive Usability Risk Analysis was performed as recommended by

- ISO 14971:2007 Medical devices - Application of Risk Management to Medical Devices.
- IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices.
- Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices (2016).

to identify critical tasks and associated user errors with the medical device's day-to-day use.

The following non-clinical performance data are provided in support of the substantial equivalence determination:

1. Verification testing to demonstrate that the software meets the established product requirement specifications and identified risk mitigation measures work as intended.
2. Verification that physiological parameters and vital sign readings collected from FDA 510k cleared third-party devices were captured, transmitted, stored, and displayed properly while maintaining data integrity (e.g. no loss of data or breaches).

All non-clinical performance tests performed on the LifePath Remote Patient Monitoring Platform passed. Non-Clinical performance data along with the substantial equivalence table prove that the LifePath Remote Patient Monitoring Platform is similar to the predicate device and the extensive risk analysis demonstrates it is as safe and effective as the predicate.

9 CLINICAL PERFORMANCE DATA

No clinical performance data was collected as a part of design validation as the Hazard Analysis performed on LifePath RMP Platform did not identify any features that will introduce hazards concerning safety and performance on the users. All known and foreseeable hazards were mitigated by implementing appropriate risk control measures. Determination of the safety and performance of LifePath Remote Monitoring Platform is based on software verification and validation testing. The verification and validation testing of the LifePath RPM Platform was found to be acceptable to support the claims of substantial equivalence. The test was based on the FDA guidance document: General Principles of Software Validation; Final Guidance for Industry and FDA Staff.

Additionally, the indications for use of the LifePath RPM Platform are similar to the predicate device which has been on the market for many years. Hence, this section does not apply to the LifePath Remote Monitoring Platform.

10 CONCLUSION

Elastic Care considers the LifePath RPM Platform to be similar to the predicate device. This conclusion is based upon similarities in indication for use, principles of operations, and technological characteristics.

Any technological differences between the LifePath RPM Platform and the predicate device do not pose any additional risk and are supported by non-clinical performance data which demonstrates that the LifePath RPM Platform will perform as intended in the specified conditions of use.