November 20, 2022

Empatica S.r.l.
Alberto Poli
Regulatory Affairs & Quality Manager
Via Stendhal, 36
Milan, 20144
Italy

Re: K221282
Trade/Device Name: Empatica Health Monitoring Platform
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DRG, FLL, LEL, GZO
Dated: November 14, 2022
Received: November 14, 2022

Dear Alberto Poli:

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,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K221282

Device Name
Empatica Health Monitoring Platform

Indications for Use *(Describe)*
The Empatica Health Monitoring Platform is a wearable device and paired mobile and cloud-based software platform intended to be used by trained healthcare professionals or researchers to remotely monitor physiologic parameters in ambulatory individuals 18 years of age and older in home-healthcare environments.

The device supports continuous data collection for monitoring the following physiological parameters:
• Peripheral skin temperature,
• Electrodermal activity,
• Blood Oxygen Saturation under no motion conditions,
• Activity associated with movement during sleep.

The Empatica Health Monitoring Platform can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

The Empatica Health Monitoring Platform is not intended for SpO2 monitoring in conditions of motion or low perfusion.

The Empatica Health Monitoring Platform is intended for peripheral skin temperature monitoring, where monitoring temperature at the wrist is clinically indicated.

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.

Empatica Srl

Traditional 510(k)

Empatica Health Monitoring Platform

Empatica Health Monitoring Platform – 510(k)

510(k) Summary

Version 3.0

Empatica Srl
Traditional 510(k)

Empatica Health Monitoring Platform

510(k) Summary

I. SUBMITTER

Company Name	Empatica Srl
Establishment Registration Number	3012933969
Contact Person	Alberto Poli, Regulatory Affairs & Quality Manager
Contact Person email	apo@empatica.com
Address	Via Stendhal, 36 - 20144, Milan, Italy
Telephone Number	+39 02 36165068
Date prepared	April 29, 2022

II. DEVICE

Trade/Proprietary Name: Empatica Health Monitoring Platform
Common/Usual Name: Remote Patient Monitoring System

Primary Product Code:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
870.2700	Oximeter	Class II	DQA	Cardiovascular

Secondary Product Codes:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
870.2910	Transmitters and Receivers, Physiological Signal, Radiofrequency	Class II	DRG	Cardiovascular
882.5050	Device, Sleep Assessment	Class II	LEL	Neurology
882.1540	Galvanic skin response measurement device	Class II	GZO	Neurology
880.2910	Thermometer, Electronic, Clinical	Class II	FLL	General Hospital

III. PREDICATE DEVICES

Predicate Device	Name	Submitter	Product Code(s)	510(k) Number
Primary	Loop System	Spry Health, Inc.	DQA BZQ	K181352
Secondary	Current Wearable Health Monitoring System	Current Health Ltd.	MSX DQA DRG BZQ FLL	K191272
Secondary	ActiGraph CentrePoint Insight Watch	ActiGraph	LEL	K181077
Secondary	Empatica E4	Empatica S.r.l.	GZO	N/A

None of these predicates have been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Empatica Health Monitoring Platform is a wearable device and software platform composed by:

- A wearable medical device called EmbracePlus,
- A mobile application running on smartphones called "Care App",
- A cloud-based software platform named "Care Portal".

The EmbracePlus is worn on the user's wrist and continuously collects raw data via specific sensors. These data are wirelessly transmitted via Bluetooth Low Energy to a paired mobile device where the Care App is up and running. The data received are analyzed by one of the Care App software modules, EmpaDSP, which computes the user physiological parameters. Based on the version of the Care App installed, the user can visualize a subset of these physiological parameters. The Care App is also responsible for transmitting, over cellular or Wi-Fi connection sensors' raw data, device information, Care App-specific information, and computed physiological parameters to the Empatica Cloud. On the Empatica Cloud, these data are stored, further analyzed, and accessible by healthcare providers or researchers via a specific cloud-based software called Care Portal.

The platform is intended to continuously monitor adult patient physiological parameters in home-healthcare environment. It is designed for monitoring patients by trained healthcare professionals or researchers. It is intended to continuously monitor blood oxygen saturation (SpO_2), peripheral skin temperature (TEMP), and electrodermal activity (EDA). Activity sensors are used to detect sleep periods and to monitor the activity associated with movement during sleep.

V. INDICATION FOR USE

The Empatica Health Monitoring Platform is a wearable device and paired mobile and cloud-based software platform intended to be used by trained healthcare professionals or researchers to remotely monitor physiologic parameters in ambulatory individuals 18 years of age and older in home-healthcare environments.

The device supports continuous data collection for monitoring of the following physiological parameters:

- Peripheral skin temperature,
- Electrodermal activity
- Blood Oxygen Saturation under no motion conditions,
- Activity associated with movement during sleep.

The Empatica Health Monitoring Platform can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

The Empatica Health Monitoring Platform is not intended for SpO2 monitoring in conditions of motion or low perfusion.

The Empatica Health Monitoring Platform is intended for peripheral skin temperature monitoring, where monitoring temperature at the wrist is clinically indicated.

I. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The application Empatica Health Monitoring Platform is substantially equivalent to the identified predicate devices. The devices have similar Indications for Use, features, technology, and accuracy.

Features	Empatica Health Monitoring Platform (Subject Device)	Loop System	Current Wearable Health Monitoring System	ActiGraph CentrePoint Insight Watch	Empatica E4	Analysis of differences
Common Name	Oximeter	Oximeter	System, Network and Communication, Physiological Monitors	Sleep assessment device (actigraphy)	Device, Galvanic Skin Response Measurement	N/A
Device Manufacturer	Empatica S.r.l.	Spry Health Ltd.	Current Health Ltd.	ActiGraph, Inc.	Empatica S.r.l.	N/A
Device Classification	II	II	II	II	II (510(k) exempt)	N/A
510(k) number	N/A	K181352	K191272	K181077	N/A	N/A
Primary Product Code	DQA	DQA	MSX	LEL	GZO	N/A
Secondary Product Code	DRG, GZO, LEL, FLL	BZQ	FLL, DQA, BZQ, DRG, BZG	-	-	N/A
Intended Use/Indications for Use	The Empatica Health Monitoring Platform is a wearable device and paired mobile and cloud-based software platform intended to be used by trained healthcare professionals or	The Loop System is intended for adult patients in the home environment for passive, noninvasive, intermittent data collection of physiological parameters that will later be transmitted to a web server for	The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or	The ActiGraph CentrePoint Insight Watch is a small worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring. The	The Empatica E4 is intended for passive, non-invasive continuous collection of electrodermal activity that will be later transmitted to a web server for remote review by	The subject device indication for use includes the monitoring of a subset of the physiological parameters of all the predicates.

Features	Empatica Health Monitoring Platform (Subject Device)	Loop System	Current Wearable Health Monitoring System	ActiGraph CentrePoint Insight Watch	Empatica E4	Analysis of differences
	researchers to remotely monitor physiologic parameters in ambulatory individuals 18 years of age and older in home-healthcare environments. The device supports continuous data collection for monitoring the following physiological parameters: • Peripheral skin temperature, • Electrodermal activity, • Blood Oxygen Saturation under no motion conditions, • Activity associated with movement during sleep	remote review by a clinician. The Loop System measures and records: • arterial oxygen saturation (SpO2) • heart rate (HR) • respiration rate (RR) All of these measurements are made when no motion is detected by the System. The Loop System device does not provide physiological alarms.	skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals. The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated. The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters in	device is intended to monitor the activity associated with movement during sleep. The Insight watch can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.	clinicians or researchers.	

Features	Empatica Health Monitoring Platform (Subject Device)	Loop System	Current Wearable Health Monitoring System	ActiGraph CentrePoint Insight Watch	Empatica E4	Analysis of differences
	The Empatica Health Monitoring Platform can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable. The Empatica Health Monitoring Platform is not intended for SpO2 monitoring in conditions of motion or low perfusion. The Empatica Health Monitoring Platform is intended for peripheral skin temperature monitoring, where monitoring		adults: • Pulse rate • Oxygen saturation • Temperature • Movement The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring, in adults, of: • Respiration rate • Non-invasive blood pressure • Lung function & spirometry • Weight The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms. The Current Wearable Health Monitoring System is not intended			

Features	Empatica Health Monitoring Platform (Subject Device)	Loop System	Current Wearable Health Monitoring System	ActiGraph CentrePoint Insight Watch	Empatica E4	Analysis of differences
	temperature at the wrist is clinically indicated.		for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor. The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion			
Target Population	Adult	Adult	Adult	Adult	Adult	The subject device and the predicates are identical

Features	Empatica Health Monitoring Platform (Subject Device)	Loop System	Current Wearable Health Monitoring System	ActiGraph CentrePoint Insight Watch	Empatica E4	Analysis of differences
Anatomical Site	Wrist	Wrist	Upper Arm	Wrist	Wrist	Clinical testing demonstrated the equivalence between the subject device and the predicates. The difference in wearing location on the body does not raise new questions of safety or efficacy.
Over the Counter or Rx	Rx	Rx	Rx	Rx	Rx	The subject device and the predicates are identical
Environment	Home	Home	Professional Healthcare Facilities & Home	Professional Healthcare Facilities & Home	Professional Healthcare Facilities & Home	The subject device includes a subgroup of the predicates, hence this does not raise new questions of safety or efficacy.

Features	Empatica Health Monitoring Platform (Subject Device)	Loop System	Current Wearable Health Monitoring System	ActiGraph CentrePoint Insight Watch	Empatica E4	Analysis of differences
Alarms	No	No	Yes	No	No	This difference does not raise new questions of safety or efficacy since the Empatica Health Monitoring Platform is not intended, by design, to include alarms to be used in a situation where the presence of alarms is a requirement for the correct patient care.
User Interface	Device screen, Mobile device application, and cloud software platform	Central station	Mobile devices and a central station	Device screen and Mobile device application	Mobile devices and cloud software platform	The differences between the subject device and the predicates do not raise new questions of safety or efficacy

Features	Empatica Health Monitoring Platform (Subject Device)	Loop System	Current Wearable Health Monitoring System	ActiGraph CentrePoint Insight Watch	Empatica E4	Analysis of differences
Energy Source	Battery	Battery	Battery	Battery	Battery	The subject device and the predicates are identical
Battery Type	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	The subject device and the predicates are identical
Wireless Communication Interface	Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud	Wireless (cellular connection) via charging station to Spry Server.	IEEE 802.11 WiFi	Bluetooth® Low Energy	Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud	All the devices are designed to transmit their data to alternate devices or sites. The different technologies used do not raise new questions of safety or efficacy
Patient contacting materials	Compliant to ISO 10993-1	Compliant to ISO 10993-1	Compliant to ISO 10993-1	Compliant to ISO 10993-1	Compliant to ISO 10993-1	The subject device and the predicates are identical

Technical and Performance Information for Blood Oxygen Saturation						
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Loop System**	**Current Wearable Health Monitoring System**	**ActiGraph CentrePoint Insight Watch**	**Empatica E4**	**Analysis of differences**
Technology	SpO2 relies on the principle that hemoglobin at different oxygenation states absorbs light differently based upon the wavelength of light.	SpO2 measured by analyzing reflectance of certain LED frequencies in a photoplethysmogram design. The diodes are mounted in the device such that they are in contact with the skin	SpO2 is measured by analyzing the reflectance of certain LED frequencies in a photoplethysmogram design. The diodes are mounted in the device such that they are in contact with the skin.	N/A	N/A	The subject device and the predicates are identical in that they all use the photoplethysmogram technology
SpO_2 Range	70-100%	70-100%	70-100%	N/A	N/A	The subject device and the predicates are identical
SpO_2 Resolution	1%	1%	1%	N/A	N/A	The subject device and the predicates are identical
SpO_2 Accuracy	2.6% A_{rms}	3% A_{rms}	± 2 Digits	N/A	N/A	The subject device and the predicates comply with ISO 80601-2-61 as well as with FDA Guidance for Pulse Oximeters (2013)

Technical and Performance Information for Temperature						
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Loop System**	**Current Wearable Health Monitoring System**	**ActiGraph CentrePoint Insight Watch**	**Empatica E4**	**Analysis of differences**
Technology	high-precision temperature sensor	N/A	In-Built Thermistor	N/A	N/A	The subject device and the predicates are identical
Temperature Range	0°C to 50°C	N/A	0°C to 50°C	N/A	N/A	The subject device and the predicates are identical
Temperature Resolution	0.1°C	N/A	0.1°C	N/A	N/A	The subject device and the predicates are identical
Temperature Accuracy	± 0.1ºC within 30.0ºC - 45.0ºC range	N/A	±0.1°C	N/A	N/A	The subject device and the predicates are identical

Technical and Performance Information for Electrodermal Activity						
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Loop System**	**Current Wearable Health Monitoring System**	**ActiGraph CentrePoint Insight Watch**	**Empatica E4**	**Analysis of differences**
Technology	EDA is measured by analyzing detected changes in the conductivity of the superficial layers of the skin.	N/A	N/A	N/A	EDA is measured by analyzing detected changes in the conductivity of the superficial layers of the skin.	The subject device and the predicates are identical
EDA Range	0.01 µS – 100 µS	N/A	N/A	N/A	0.01 µS – 100 µS	The subject device and the predicates are identical
EDA Resolution	1 digit ~ 55 pS	N/A	N/A	N/A	1 digit ~ 900 pS	This difference shall not raise new concerns of device safety or effectiveness

Technical and Performance Information for Activity and Sleep						
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Loop System**	**Current Wearable Health Monitoring System**	**ActiGraph CentrePoint Insight Watch**	**Empatica E4**	**Analysis of differences**
Technology	Accelerometer	N/A	N/A	Accelerometer	N/A	The subject device and the predicate are identical
Accelerometer Type	Microelectromechanical system (MEMS)-based integrated circuit	N/A	N/A	Microelectromechanical system (MEMS)-based integrated circuit	N/A	The subject device and the predicate are identical
Accelerometer Sampling Rate	Digital method, 26 Hz – 208 Hz	N/A	N/A	Digital method, 32 Hz – 256 Hz	N/A	This difference shall not raise new concerns of device safety or effectiveness
Accelerometer Dynamic Range	± 16 g	N/A	N/A	± 8 g	N/A	This difference shall not raise new concerns of device safety or effectiveness
Accelerometer Sensitivity	0.488 milli-g per Least Significant Bit	N/A	N/A	2.4 milli-g per Least Significant Bit	N/A	This difference shall not raise new concerns of device safety or effectiveness

II. PERFORMANCE DATA

Non-Clinical testing (Bench testing)

The following non-clinical (bench) testing was conducted to support a determination of substantial equivalence to the predicates and to demonstrate performance. The non-clinical bench tests included:

Test Name	Test Description	Results
Biocompatibility testing	The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" September 4, 2020, and International Standard ISO 10993-1:2018 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests: ● Cytotoxicity ● Sensitization ● Irritation The EmbracePlus wearable device is considered surface contacting for a prolonged duration (>24 hours < 30 days)	Passed
Electrical safety testing	The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with International Standard IEC 60601-1 for electrical safety	Passed
Electromagnetic compatibility (EMC) testing	The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with International Standard IEC 60601-1-2 for EMC	Passed
Wireless Radio Communication	Empatica Health Monitoring Platform was tested to ensure it can communicate via wireless radio in its intended environment in compliance with FDA Radio Frequency Wireless Technology in Medical Devices Guidance, issued August 2013	Passed
Usability testing	The Empatica Health Monitoring Platform was assessed with regards to usability for compliance with IEC 62366-1. The EmbracePlus was also tested in accordance with International Standard IEC 60601-1-11 for Usability of medical devices.	Passed
Home-Use testing	The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with International Standard IEC 60601-1-6 for medical devices used in home healthcare environments.	Passed
Cleaning validation	The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with International Standard ISO 17664 and AAMI TIR 30 to assess device cleaning procedure	Passed
Manual disinfection	The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with ASTM E1837:2014 and AAMI TIR 12 to assess device low-level disinfection procedure	Passed
Temperature measurement accuracy	The Empatica Health Monitoring Platform was tested to confirm the Skin temperature measurement accuracy and transient time complies with ISO 80601-2-56 Medical electrical equipment - Part 2-56:	Passed

Test Name	Test Description	Results
	Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)] to assess its accuracy.	
Electrodermal activity measurement	The Empatica Health Monitoring Platform computed electrodermal activity (EDA) was tested to determine its equivalence to the predicate device Empatica E4.	Passed
Activity Counts/Sleep	Bench testing has been performed to demonstrate the equivalence of the Empatica Health Monitoring Platform activity counts and sleep detection with the predicate device.	Passed

Software Verification and Validation Testing

Software verification and validation testing were conducted. Documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." All the Empatica Health Monitoring Platform software components were considered a "moderate" level of concern since a failure or latent flaw in the software could result in minor injury to the patient or operator.

Cybersecurity

Cybersecurity activities was conducted. Documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, " Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." All the Empatica Health Monitoring Platform software components underwent appropriate cybersecurity assessment and testing.

Animal study

No animal studies were conducted as part of the submission to prove substantial equivalence.

Clinical Study

A human clinical investigation study was conducted to demonstrate the performance of the Empatica Health Monitoring Platform.

The clinical study investigated the accuracy of the blood oxygen saturation monitoring in 13 healthy adult subjects with heterogeneous skin types. The Empatica Health Monitoring Platform was compared to the gold standard, arterial blood gas analysis.

This testing was conducted in accordance with ISO 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment and in accordance with the FDA Guidelines for Pulse Oximeters – Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff (2013).

The Empatica Health Monitoring Platform was found to be in compliance with both documents. This testing demonstrated an accuracy of 2.6% A_{rms} across the SpO_2 range of 70-100%. This testing was not conducted in the presence of motion or low perfusion.

No adverse events related to the device were encountered during the execution of both studies. The results of the clinical investigations demonstrate an effectiveness profile similar to the predicate devices.

III. CONCLUSION

Based on the information presented in this 510(k) premarket notifications, the Empatica Health Monitoring Platform is substantially equivalent to the predicate devices. The Empatica Health Monitoring Platform is as safe and effective as the currently marketed predicate devices.

Based on testing and comparison with the predicate devices, the Empatica Health Monitoring Platform indicated no adverse indications or results. It is our determination that the Empatica Health Monitoring Platform is safe, effective and performs within its design specifications, and is substantially equivalent to the predicate devices.