March 27, 2020

Siemens Healthcare Diagnostics, Inc.
Lois Parillon
Regulatory Technical Specialist
2 Edgewater Drive
Norwood, MA 02062

Re: K192240
Trade/Device Name: RAPIDPoint® 500e Blood Gas System
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, KHP, JGS, CEM, JFP, CGZ, CGA, GKR, MQM
Dated: February 24, 2020
Received: February 26, 2020

Dear Lois Parillon:

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 and Part 809); 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,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192240

Device Name

RAPIDPoint® 500e Blood Gas System

Indications for Use *(Describe)*

The RAPIDPoint® 500e Blood Gas System is intended for in vitro diagnostic use and is designed to provide the determination in whole blood for the following parameters:

- Partial pressure of carbon dioxide
- Partial pressure of oxygen
- pH
- Sodium
- Potassium
- Ionized Calcium
- Chloride
- Glucose
- Lactate
- Total Hemoglobin and fractions: *F*O2Hb, *F*COHb, *F*MetHb, *F*HHb
- Neonatal Bilirubin

The RAPIDPoint 500e Blood Gas System is also intended for in vitro testing of pleural fluid samples for the pH parameter. The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions and are exudative in nature. This test system is intended for use in point of care or laboratory settings.

The following list includes the **Indications for Use** information for each analyte measured on the RAPIDPoint 500e Blood Gas System:

Lactate: A lactic acid test system is a device intended to measure lactic acid in whole blood. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Neonate Bilirubin: A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

pCO2, p02, pH: Measurements of blood gases (pCO2, p02) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium: Sodium measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium: Potassium measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride: Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Ionized calcium: Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Glucose: Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Total hemoglobin: Total hemoglobin measurements are used to determine the hemoglobin content of human blood.

Oxyhemoglobin: Oxyhemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

Carboxyhemoglobin: Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

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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Section 5 – 510(k) SUMMARY

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

1.0 SUBMITTER INFORMATION

Submitter	**Siemens Healthcare Diagnostics, Inc.** Point of Care (POC) Diagnostics 2 Edgewater Drive Norwood, MA 02062
Contacts:	**Primary**: **Lois Parillon** Regulatory Affairs Technical Specialist EMAIL: lois.parillon@siemens-healthineers.com PHONE: 781-269-3917 FAX: 781-269-3599
	Alternative: **Amy Goldberg** Senior Manager Regulatory Affairs EMAIL: amy.goldberg@siemens-healthineers.com PHONE: 781-269-3544 FAX: 781-269-3599
Date Summary Prepared	March 26, 2020

2.0 DEVICE INFORMATION

Proprietary Name	**RAPIDPoint® 500e Blood Gas System**
Common Name	**Blood Gases (pCO_2, pO_2) and Blood pH Test System**

3.0 REGULATORY INFORMATION

Table 5-1 below highlights the classification and regulatory information for all analytes that are measured on the RAPIDPoint 500e Blood Gas System, which is unchanged from the legally marketed predicate device: RAPIDPoint 500 System.

5-1 Regulatory Information- Classification					
Measured Analytes	**Classification Name**	**Regulation Section**	**Product Code**	**Device Class**	**Classification Panel**
pCO_2, pO_2, pH	Blood gases (pCO_2, pO_2) and blood pH test system	21 CFR § 862.1120	CHL	II	Clinical Chemistry (75)
Sodium (Na^+)	Sodium test system	21 CFR § 862.1665	JGS	II	
Potassium (K^+)	Potassium test system	21 CFR § 862.1600	CEM	II	
Ionized Calcium (Ca^{2+})	Calcium test system	21 CFR § 862.1145	JFP	II	
Chloride (Cl^-)	Chloride test system	21 CFR § 862.1170	CGZ	II	
Glucose (Glu)	Glucose test system	21 CFR § 862.1345	CGA	II	
Total hemoglobin (tHb)	Automated hemoglobin system	21 CFR § 864.5620	GKR	II	
Neonatal bilirubin	Bilirubin in the neonate test system	21 CFR § 862.1113	MQM	I	
Lactate (Lac)	Lactic acid test system	21 CFR § 862.1450	KHP	I	

4.0 DEVICE DESCRIPTION

The RAPIDPoint 500e Blood Gas System is a compact, bench-top analyzer designed for in vitro diagnostic testing and is suitable for professional use in a point-of-care or central laboratory environment. This system measures the following: blood gases, electrolytes, metabolites, total hemoglobin, and hemoglobin derivatives in arterial, venous, and capillary whole blood samples. Additionally, the RAPIDPoint 500e Blood Gas System measures pH in pleural fluid.

The RAPIDPoint 500e Blood Gas System incorporates a cartridge-based design with no external reagent bottles or gas tanks. The system uses self-contained measurement and wash/waste cartridges that are replaced when depleted. The system automatically calibrates the measurement sensors and reports results within 60 seconds for display on a color touch screen for easy viewing.

5.0 INTENDED USE STATEMENT

The RAPIDPoint 500e Blood Gas System is intended for in vitro diagnostic use and is designed to provide the determination in whole blood for the following parameters:

- Partial pressure of carbon dioxide
- Partial pressure of oxygen
- pH
- Sodium
- Potassium
- Ionized Calcium
- Chloride
- Glucose
- Lactate
- Total Hemoglobin and fractions: FO_2Hb, *F*COHb, *F*MetHb, *F*HHb
- Neonatal Bilirubin

The RAPIDPoint 500e Blood Gas System is also intended for in vitro testing of pleural fluid samples for the pH parameter. The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions and are exudative in nature. This test system is intended for use in point of care or laboratory settings.

The following list includes the Indications for Use information for each analyte measured on the RAPIDPoint 500e Blood Gas System:

Lactate: A lactic acid test system is a device intended to measure lactic acid in whole blood. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Neonate Bilirubin: A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

***p*CO₂, *p*O₂, pH:** Measurements of blood gases (pCO_2, pO_2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium: Sodium measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium: Potassium measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride: Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Ionized calcium: Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Glucose: Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Total hemoglobin: Total hemoglobin measurements are used to determine the hemoglobin content of human blood.

Oxyhemoglobin: Oxyhemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

Carboxyhemoglobin: Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

6.0 SPECIAL CONDITIONS FOR USE STATEMENT(S):

- For prescription use only
- For in vitro diagnostic use only
- For point-of-care (POC) or clinical laboratory settings

7.0 REASON FOR SUBMISSION

This Special 510(k) is being filed to seek FDA clearance for the RAPIDPoint 500e Blood Gas System, a modified version of the existing RAPIDPoint 500 System, which is currently cleared. A design change was made to update the Operating System (OS) software from Microsoft Windows 7 Embedded to Windows 10 IoT (Internet of Things), which is the primary reason for this Special 510(k) submission. The following minor enhancements/modifications will be introduced with the RAPIDPoint 500e Blood Gas System:

NON-SOFTWARE RELATED:

A. Updated exterior (skins) and display screen (user interface) design with new color scheme for Siemens Healthineers branding.

B. Updated the following instrument main board parts due to obsolescence:

- ETX (Embedded Technology eXtended)
- FPGA (Field Programmable Gate Array)
- CPLD (Complex Programmable Logic Device)

SOFTWARE RELATED:

5-2	New Features in RAPIDPoint 500e Software Version 5.0
1	Upgrading the operating system to Windows embedded (IoT) 10 Operating System (Enterprise)
2	Support of 1D and 2D barcodes (onboard and external barcode scanners)
3	Updated User Interface assets with new colors / branding design
4	Sodium sensor interferent detected message
6	Encrypted data transmission with POCcelerator (Cybersecurity enhancements)
7	USB port ON/OFF capability (Cybersecurity enhancements)
8	Required QC after cartridge change
9	Notification when AQC is disabled
10	AQC automatic printing
11	Restricted QC Override

A Special 510(k) Premarket Notification is the ideal pathway for this submission based on the following:

- There is no change to the intended use or indications for use.
- There is no change to the fundamental scientific technology.
- There is no change to labeled performance claims.
- There is no change to principle of operation.
- There is no change to cartridge calibrator formulation and technology.

8.0 SUBSTANTIAL EQUIVALENCE INFORMATION

5-3 Predicate Device Information	
ELEMENT	**PREDICATE DEVICE**
Predicate Device Name	RAPIDPoint 500 System
Common Name	Blood Gasses (pCO_2) (pO_2) and Blood pH Test System
FDA Product Codes	CHL, JGS, CEM, JFP, CGZ, CGA, GKR, MQM, KHP
510(k) Number	K122539
Manufacturer	Siemens Healthcare Diagnostics Inc.

The RAPIDPoint 500e Blood Gas System is substantially equivalent in intended use/indications for use, fundamental scientific technology, reagents, principle of operation, and performance claims to the predicate device. **Table 5-4** below lists the similarities and differences between the RAPIDPoint 500e Blood Gas System and the RAPIDPoint 500 System (Predicate device), respectively.

5-4 Substantial Equivalency		
FEATURE	RAPIDPoint 500 System **(PREDICATE DEVICE)**	RAPIDPoint 500e Blood Gas System **(MODIFIED DEVICE)**
Intended Use	The RAPIDPoint 500 System is intended for in vitro diagnostic use and is designed to provide the determination in whole blood for the following parameters: • Partial pressure of carbon dioxide • Partial pressure of oxygen • pH • Sodium • Potassium • Ionized Calcium • Chloride • Glucose • Lactate • Total Hemoglobin and fractions: FO_2Hb, *F*COHb, *F*MetHb, *F*HHb • Neonatal Bilirubin The RAPIDPoint 500 System is also intended for in vitro testing of pleural fluid samples for the pH parameter. The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions. The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions and are exudative in nature. This test system is intended for use in point of care or laboratory settings. The following list includes the Indications for Use information for each analyte measured on the RAPIDPoint 500e Blood Gas System: **Lactate:** A lactic acid test system is a device intended to measure lactic acid in whole blood. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).	Same

5-4 Substantial Equivalency		
FEATURE	RAPIDPoint 500 System **(PREDICATE DEVICE)**	RAPIDPoint 500e Blood Gas System **(MODIFIED DEVICE)**
	Neonate Bilirubin: A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus). **pCO2, p02, pH:** Measurements of blood gases (pCO2, p02) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances. **Sodium:** Sodium measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. **Potassium:** Potassium measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. **Chloride:** Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis. **Ionized calcium:** Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).	

5-4 Substantial Equivalency		
FEATURE	RAPIDPoint 500 System **(PREDICATE DEVICE)**	RAPIDPoint 500e Blood Gas System **(MODIFIED DEVICE)**
	Glucose: Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. **Total hemoglobin:** Total hemoglobin measurements are used to determine the hemoglobin content of human blood.	
Sample Type	• Whole blood (Arterial, Venous and Capillary for all analytes) • Pleural Fluid (for pH only)	Same
Sample Volume	• 100 µL (capillary) • 200 µL (syringe)	Same
Principle of Measurement	**ELECTROCHEMISTRY**: **Analytes: (pH, Ca^{++}, pCO_2, pO_2, Na^+, K^+, Cl^-, Glucose, Lactate)** Potentiometry, amperometry & conductimetric methods to convert the potential generated by the sensor to an electrical signal. **OPTICAL:** **(Co-ox Fractions and Neonatal Bilirubin)** Automated co-oximetry using spectral analysis from on-board visible absorption	Same
Sensors	Contained in Measurement Cartridges	Same
Reagent Consumables	Measurement Cartridge AutomaticQC Cartridge Waste/Wash Cartridge	Same
Quality Control	Manual and automatic	Same
Calibration	1-point, 2-point and full calibration using automated on-board reagent.	Same

5-4 Substantial Equivalency		
FEATURE	RAPIDPoint 500 System **(PREDICATE DEVICE)**	RAPIDPoint 500e Blood Gas System **(MODIFIED DEVICE)**
Operating System Software	Windows 7 Embedded Operating System	Windows 10 IoT (Internet of Things) Enterprise embedded Operating System
Barcode	Integrated – 1D, 2D External – 1D	Integrated – same External – 1D, 2D
Exterior Design		**UPDATED** exterior (skins) and display screen (user interface) design with new color scheme for Siemens Healthineers branding.  ***No change to workflow.***

9.0 RISK MANAGEMENT

The Risk Management was performed in compliance with EN ISO 14971:2012 ***Medical Devices – Application of Risk Management to Medical Devices***. A series of risk assessments were performed in order to identify, or mitigate any potential risks associated to the design changes for the modified device. In addition, a ***Failure Mode, Effects and Criticality Analysis (FMECA)*** is performed for any identifiable risks.

10.0 VERIFICATION AND VALIDATION SUMMARY

All verification and validation activities were performed in accordance to relevant standards, established plans and protocols and Siemens Design Control procedures. Testing verified all acceptance criteria were met.

11.0 CYBERSECURITY INFORMATION

Cybersecurity design inputs for the RAPIDPoint 500e Blood Gas System were established as part of the Siemens Quality Management procedures for software validation and risk analysis activities. Risks were identified, assessed and controls were designed within the software, to

mitigate potential security threats, system vulnerabilities, viral attacks and safeguard unauthorized access to patient data. The updated cybersecurity controls included in the RAPIDPoint 500e software are primarily designed to minimize risks to patients as in the cleared RAPIDPoint 500 System.

12.0 SUBSTANTIAL EQUIVALENCE STATEMENT

The RAPIDPoint 500e Blood Gas System shares identical intended use, indications for use, fundamental scientific technology, reagents, principle of operation, and performance claims to the predicate device, the RAPIDPoint 500 System. Performance testing results were also comparable. The similarities in these technical features and performance testing results demonstrate that, the RAPIDPoint 500e Blood Gas System (modified device) is substantially equivalent to the predicate device, the RAPIDPoint 500 System.

13.0 CONCLUSION

The performance of the RAPIDPoint 500e Blood Gas System is substantially equivalent to the comparative method.