June 5, 2020

Epocal Inc.
Amy Goldberg
Sr. Manager, Regulatory Affairs
2060 Walkley Road
Ottawa, K1G 3P5 Canada

Re: K200107
Trade/Device Name: epoc® Blood Analysis 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, JGS, CEM, JFP, JPI, CGA, KHP, CGL, CGZ, CDS, JFL
Dated: May 1, 2020
Received: May 7, 2020

Dear Amy Goldberg:

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, M.T., 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

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)*
k200107

Device Name
epoc® Blood Analysis System

Indications for Use *(Describe)*

The **epoc Blood Analysis System** is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous, or capillary whole blood in the laboratory or at the point of care.

The **Blood Gas Electrolyte and Metabolite (BGEM) Test Card** panel configuration includes sensors that quantitate pH, *p*CO2, *p*O2, Sodium, Potassium, Ionized Calcium, Chloride, Total Carbon Dioxide, Glucose, Lactate, Blood Urea Nitrogen, Creatinine, and Hematocrit.

pH, *p*CO2, *p*O2 (blood gases) measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium and **Potassium** measurements from the epoc Blood Analysis System are used in diagnosis and treatment of diseases involving electrolyte imbalance.

Ionized Calcium measurements from the epoc Blood Analysis System are used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Total Carbon Dioxide measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of disorders associated with changes in body acid-base balance.

Glucose measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell tumors.

Lactate measurements from the epoc Blood Analysis System are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Blood Urea Nitrogen measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of certain renal and metabolic diseases.

Creatinine measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of certain renal diseases and in monitoring renal dialysis.

Hematocrit measurements from the epoc Blood Analysis System are used to distinguish normal from abnormal states of blood volume, such as anemia and erythrocytosis.

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 Name:	**Epocal Inc., a Siemens Healthineers Company** **2060 Walkley Road** **Ottawa, ON K1G 3P5** **Canada**
Company Contacts:	**Amy Goldberg** Sr. Manager, Regulatory Affairs Email: amy.goldberg@siemens-healthineers.com Phone: +1 (781) 269-3544 **Amanda Barriage** Regulatory Affairs Manager Email: amanda.barriage@siemens-healthineers.com Phone: +1 (613) 688 3982 ext. 2232
Date Prepared:	June 4, 2020

2.0 DEVICE INFORMATION

Trade or Proprietary Name:	epoc® Blood Analysis System
Common Name:	Blood Gases (PCO2, PO2) and Blood pH Test System

3.0 REGULATORY INFORMATION

The following table highlights the classification and regulatory information for all analytes that are measured on the epoc® Blood Analysis System, which is unchanged for this Special 510(k) submission.

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
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**	
Creatinine (Crea)	Creatinine test system	21 CFR § 862.1225	CGL	**II**	
Hematocrit (Hct)	Hematocrit measuring device	21 CFR § 862.6400	JPI	**II**	
Lactate (Lac)	Lactic acid test system	21 CFR § 862.1450	KHP	**I**	
Blood Urea Nitrogen (BUN)	Urea nitrogen test system	21 CFR § 864.6150	CDS	**II**	
Total Carbon Dioxide (TCO_2)	Bicarbonate/carbon dioxide test system	21 CFR § 862.1160	JFL	**II**	
Capillary blood collection tube	Capillary blood collection tube	21 CFR § 864.6150	GIO	**I**	Hematology

4.0 DEVICE DESCRIPTION

The epoc® Blood Analysis System is an in vitro diagnostic device system for the quantitative testing of blood gases, electrolytes, and metabolites in venous, arterial, and capillary whole blood samples. The epoc® System is comprised of three (3) major subsystems: epoc® Host, epoc® Reader and epoc® BGEM Test Card.

- **epoc® Blood Gas Electrolyte Metabolite (BGEM) Test Card**: single-use, device with port for blood sample introduction which contains the sensor configurations for testing Sodium (Na+), Potassium (K+), Calcium (Ca++), Chloride (C)l-, pH, partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), Glucose (Glu), Lactate (Lact), Creatinine (Crea), Hematocrit (Hct), Blood Urea Nitrogen (BUN) and Total Carbon Dioxide (TCO_2).

- **epoc® Reader:** portable, battery-powered device component that measures electrical signals from the test card sensors during blood testing and transmits this sensor data wirelessly via Bluetooth to the epoc Host.

- **epoc® Host:** mobile computer-based device component for calculating test results from the sensor data sent by the epoc Reader and displaying these results on the graphical user interface. The epoc Host component can be physically connected to the Reader by a cradle component. The epoc Host also incorporates an internal laser barcode scanner for scanning patient and operator IDs. The epoc Host component currently runs on Microsoft® Windows Mobile 6.5 Operating System (OS).

The epoc® Blood Analysis System was previously cleared for prescription use to quantitate Sodium (Na+), Potassium (K+), Calcium (Ca++), Chloride (C)l-, pH, partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), Glucose (Glu), Lactate (Lact), Creatinine (Crea), Hematocrit (Hct), Blood Urea Nitrogen (BUN) and Total Carbon Dioxide (TCO_2) in arterial, venous, and capillary blood samples per k061597, k090109, k092849, k093297, k113726 and k171247.

This Special 510(k) submission has been prepared to introduce hardware and software updates to the current epoc® Host component only.

5.0 INTENDED USE

The epoc® Blood Analysis System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care.

The Blood Gas Electrolyte and Metabolite (BGEM) Test Card panel configuration includes sensors that quantitate pH, pCO2, pO2, Sodium, Potassium, Ionized Calcium, Chloride, Total Carbon Dioxide, Glucose, Lactate, Blood Urea Nitrogen, Creatinine, and Hematocrit.

6.0 INDICATIONS FOR USE

pH, pCO2, p02 (blood gases) measurements from the epoc® Blood Analysis System are used in the diagnosis and treatment of life-threatening acid-base disturbances.
Sodium and **Potassium** measurements from the epoc® Blood Analysis System are used in diagnosis and treatment of diseases involving electrolyte imbalance.
Ionized Calcium measurements from the epoc® Blood Analysis System is used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.
Chloride measurements from the epoc® Blood Analysis System are used in the diagnosis and treatment of electrolyte and metabolic disorders.
Total Carbon Dioxide measurements from the epoc® Blood Analysis System are used in the diagnosis and treatment of disorders associated with changes in body acid-base balance.

Glucose measurements from the epoc® Blood Analysis System are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, and idiopathic hypoglycemia, and of pancreatic islet cell tumors.
Lactate measurements from the epoc® Blood Analysis System are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).
Blood Urea Nitrogen measurements from the epoc® Blood Analysis System are used in the diagnosis and treatment of certain renal and metabolic diseases.
Creatinine measurements from the epoc® Blood Analysis System are used in the diagnosis and treatment of certain renal diseases and in monitoring renal dialysis.
Hematocrit measurements from the epoc® Blood Analysis System distinguishes normal from abnormal states of blood volume, such as anemia and erythrocytosis.

7.0 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.

8.0 REASON FOR SUBMISSION

This Special 510(k) submission has been prepared to introduce hardware and software updates to the current epoc Host component only. The current epoc Host hardware component is a dedicated-use Personal Digital Assistant (PDA) computer-based platform that operates on Microsoft® Windows Mobile 6.5 Operating System (OS). The hardware component is changing to a new tablet-based mobile platform running on Android 9.0 OS. The modified device consists of the existing current epoc Reader and current epoc Test Card along with a new epoc Host component. There is no change to the epoc Reader and Test Card. The epoc Host Application Software has been modified to support the Android-based Operating System. The new Host component is referred to as “epoc NXS Host” throughout this submission.

The epoc® Blood Analysis System with current Host component is the Predicate Device (k061597) for this Special 510(k) submission. Both the current epoc Host and new epoc NXS Host mobile computers are intended to have equivalent functionalities and workflow. 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 (test card) calibrator formulation and technology.

9.0 SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Device Information				
ELEMENT	**PREDICATE DEVICE**			
Predicate Device Name	epoc® Blood Analysis System			
Common Name	Blood gases (PCO2, PO2) and blood pH test system			
510(k) Numbers	K092849, K093297, K113726, K171247			
FDA Product Codes and Analytes per 510(k) Clearance	K092849	K093297	K113726	K171247
	CHL: pH, pCO_2, pO_2 JGS: Sodium CEM: Potassium JFP: Ionized Calcium JPI: Hematocrit CGA: Glucose	KHP: Lactate	CGL: Creatinine CGZ: Chloride	CDS: Blood Urea Nitrogen JFL: Total Carbon Dioxide
	Sample Types: heparinized or un-anticoagulated arterial, venous or capillary whole blood			
Manufacturer	Epocal Inc., a Siemens Healthineers Company			

The Substantial Equivalency Table in the following pages summarizes the similarities and differences between the epoc® Blood Analysis System with NXS Host (Modified device) and the epoc® Blood Analysis System (Predicate device).

Substantial Equivalency		
FEATURE	epoc® Blood Analysis System with NXS Host **(MODIFIED DEVICE) K200107**	epoc® Blood Analysis System **(PREDICATE DEVICE) K092849, K093297, K113726, K171247**
Intended Use	The epoc® Blood Analysis System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care. The Blood Gas Electrolyte and Metabolite (BGEM) Test Card panel configuration includes sensors that quantitate • pH • pCO2 • pO2 • Sodium • Potassium • Ionized Calcium • Chloride • Total Carbon Dioxide • Glucose • Lactate • Blood Urea Nitrogen • Creatinine • Hematocrit	Same
FDA Product Codes and Analytes per 510(k) Clearance	**K092849:** CHL: pH, pCO_2, pO_2 JGS: Sodium CEM: Potassium JFP: Ionized Calcium JPI: Hematocrit CGA: Glucose **K093297:** KHP: Lactate **K113726:** CGL: Creatinine CGZ: Chloride **K171247:** CDS: Blood Urea Nitrogen JFL: Total Carbon Dioxide	Same

Substantial Equivalency		
FEATURE	epoc® Blood Analysis System with NXS Host **(MODIFIED DEVICE) K200107**	epoc® Blood Analysis System **(PREDICATE DEVICE) K092849, K093297, K113726, K171247**
Sample Type	Heparinized or un-anticoagulated arterial, venous or capillary whole blood	Same
Sample Volume	At least 92µL	Same
Measurement Technology	An electrochemical multi-sensor array integrated into a single-use test that is interpreted by a handheld reader and associated software	Same
Sensors	Contained in Test Cards	Same
Calibration	Calibration using in-card calibration fluid.	Same
Operating System Software	Android 9.0 Operating System	Windows 6.5 Mobile Operating System
Hardware	**epoc Host:** Dedicated-use tablet-based mobile platform  **epoc Test Card**: same **epoc Reader**: same	**epoc Host:** Dedicated-use Personal Digital Assistant (PDA) mobile computer-based platform  **epoc Test Card**: contains an array of sensors on a sensor module mounted in a credit-card sized fluidic housing with a sample entry port, and a sealed calibrator fluid reservoir. **epoc Reader**: Portable, battery-powered device for reading Test Cards
Connectivity	Wireless Bluetooth	Same

Substantial Equivalency		
FEATURE	epoc® Blood Analysis System with NXS Host **(MODIFIED DEVICE) K200107**	epoc® Blood Analysis System **(PREDICATE DEVICE) K092849, K093297, K113726, K171247**
Barcode Scanner	epoc Reader: Integrated LED (1D) used to read the Test Card Barcode epoc Host: Integrated (1D & 2D) Manufacturer: Zebra Module model #: SE4710 Sensor resolution: 1280 x 800 pixels	epoc Reader: Same epoc Host: Integrated (1D & 2D) Manufacturer: Zebra Module model #: SE4500DL Sensor resolution: 752 x 480 pixels

10.0 RISK MANAGEMENT

The Risk Management was performed in compliance with EN ISO 14971:2012 and ISO 14971:2007 ***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.

The conclusion of the risk management process is that the overall residual risk of the epoc System with the epoc NXS host is acceptable.

11.0 VERIFICATION AND VALIDATION SUMMARY

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

No performance data was required to evaluate the changes introduced with the alternate epoc Host component. Software, hardware and usability validation were adequate to support substantial equivalence.

12.0 CYBERSECURITY INFORMATION

Cybersecurity design inputs for the epoc® Blood Analysis System with NXS Host were established as part of the 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.

13.0 CONCLUSION

Results from verification and validation testing confirmed that the modifications made to epoc® Host hardware, operating system, and system software do not introduce new concerns for safety and effectiveness. The modified device utilizes the same intended use, indications for use, principle of operation, workflow, scientific technology and core algorithm as the predicate device. The epoc Test Card and epoc Reader remains unchanged from the predicate device. Based on these factors, the epoc® Blood Analysis System with NXS Host (Modified device) is substantially equivalent to the previously cleared predicate device, the epoc® Blood Analysis System.