January 17, 2018

Epocal Inc.
Jennifer Armstrong
Regulatory Affairs Manager
2060 Walkley Road
Ottawa, ON K1G 3P5 Canada

Re: K171247
Trade/Device Name: epoc Blood Urea Nitrogen Test, epoc Total Carbon Dioxide Test
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: II
Product Code: CDS, JFL
Dated: December 11, 2017
Received: December 13, 2017

Dear Jennifer Armstrong:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171247

Device Name
epoc® Blood Urea Nitrogen Test
epoc® Total Carbon Dioxide Test

Indications for Use *(Describe)*
The Blood Urea Nitrogen and Total Carbon Dioxide tests, as part of 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.

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

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.

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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epocal Inc.

510(k) SUMMARY K171247

GENERAL INFORMATION

Applicant Name:	Epocal Inc. 2060 Walkley Road Ottawa, ON K1G 3P5 Canada
Company Contact:	Jennifer Armstrong Manager, Regulatory Affairs Phone: (613) 688-3982 x2227 Email: jennifer.armstrong@alere.com
Date Prepared:	January 15, 2018

DEVICE IDENTIFICATION

Trade or Proprietary Names:	epoc® Blood Urea Nitrogen Test epoc® Total Carbon Dioxide Test

REGULATORY INFORMATION

Classification Regulation:	21 CFR 862.1770	Urea nitrogen test system
	21 CFR 862.1160	Bicarbonate/carbon dioxide test system
Regulatory Class:	Class II	
Product Codes:	CDS	Electrode, Ion Specific, Urea Nitrogen
	JFL	pH Rate Measurement, Carbon-Dioxide
Predicate Device:	i-STAT CHEM8+ Cartridge (K053110; cleared by i-STAT Corporation)	

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 3 major subsystems: epoc Host, epoc Reader and epoc BGEM Test Card. The main accessory used with the epoc System includes the epoc Care-Fill Capillary Tubes used to collect and introduce capillary blood samples into the epoc Test Card.

The epoc Blood Analysis System was previously cleared for prescription use to quantitate pH, pCO_2, pO_2, Na, K, iCa, Cl, Glu, Lact, Crea, and Hct in arterial, venous, and capillary blood samples per k061597, k090109, k092849, k093297, and k113726. This premarket notification submission adds blood urea nitrogen (BUN) and total carbon dioxide (TCO_2) quantitation to the epoc BGEM Test Card and Blood Analysis System.

INTENDED USE

The Blood Urea Nitrogen and Total Carbon Dioxide tests, as part of 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.

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

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.

COMPARISON WITH PREDICATE

Attribute	**Predicate Device** **i-STAT CHEM8+ Cartridge (with i-STAT Portable Clinical Analyzer) [k053110]**	**Candidate Device** **epoc BGEM Test Card with epoc Blood Analysis System**
Intended use	Portable, prescription use test system	Prescription, point-of-care test system
Measured Parameter	Urea Nitrogen (BUN); Total CO_2 (TCO_2)	Blood Urea Nitrogen (BUN); Total CO_2 (TCO_2)
Calculated Parameter	Anion Gap (AnGap);	Anion Gap (AGap, AGapK); BUN/Creatinine ratio (BUN/Crea)
Where used	hospital, point of care	Same
Sample type	Venous, arterial and capillary whole blood	Same
Technology	An electrochemical multi-sensor array integrated into a single-use test that is interpreted by a handheld reader and associated software	Same
Reportable ranges (BUN and TCO_2)	BUN 3-140 mg/dL TCO_2 5-50 mmol/L	BUN 3-120 mg/dL TCO_2 same
Sample volume	95 µL	At least 92 µL

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity

This study evaluated and verified the performance of the epoc Blood Analysis System for BUN and TCO_2 quantitation at the low end of their respective concentration ranges by determining the Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) according to CLSI EP17-A2. Test samples were prepared from dialyzed whole blood. Results from this study are shown below:

Analyte	LoB	LoD	LoQ
BUN	2 mg/dL	3 mg/dL	3 mg/dL
TCO_2	4.0 mM	4.3 mM	4.3 mM

2. Linearity

Linearity was performed in-house on multiple whole blood samples with BUN or TCO_2 values spanning the reportable range. Linearity is reported versus theoretical BUN values based on gravimetric mixtures of high and low BUN samples (as measured using an in-house standard whole blood BUN method). Three card lots were used in this study. The study was conducted per CLSI EP06-A.

BUN			
Test Range	**Slope**	**Intercept**	**R**
4-119 mg/dL	1.020	0.4	0.9989
TCO_2			
Test Range	**Slope**	**Intercept**	**R**
4-49 mmol/L	0.903	3.32	0.9997

3. Precision (Aqueous Controls)

Analytical precision for BUN and TCO_2 measurements was conducted with four card lots using at least 25 epoc Readers where replicate measurements were run in-house twice a day for twenty days for each fluid per CLSI EP05-A3. In the precision data tables below, S_{WR} denotes within-run standard deviation, $\%CV_{WR}$ denotes within-run coefficient of variation, S_T denotes total standard deviation, and $\%CV_T$ denotes total coefficient of variation.

Aqueous Control	Units	N	Mean	S_{WR}	$\%CV_{WR}$	S_T	$\%CV_T$
High Level (BUN)	mg/dL	320	51.7	1.01	2.0%	1.16	2.3%
Low Level (BUN)	mg/dL	320	7.1	0.30	4.2%	0.32	4.5%
High Level (TCO_2)	mmol/L	320	30.7	0.82	2.7%	0.92	3.0%
Low Level (TCO_2)	mmol/L	320	16.2	0.88	5.4%	1.02	6.3%

4. Interference

Interferent testing of the BUN and TCO_2 measurements on the epoc System was performed as recommended in the CLSI guideline EP07-A2. In each of these tests, human serum specimens were aliquoted into two (2) samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The bias between the mean of six (6) replicates on both the control sample and the test sample with added interferent was calculated. Unacceptable interference bias was defined as producing a significant error more than 5% of the time.

Clinically significant interfering substances for BUN measurements are itemized below:

- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause elevated BUN results. For proper line-flushing procedures refer to CLSI H11-A4.
- Citrate will have no significant effect up to 6.0 mmol/L (176.5 mg/dL) after which it will decrease the BUN concentration by up to 0.26 mg/dL BUN per mmol/L citrate.
- EDTA will have no significant effect up to 4.5 mmol/L (167 mg/dL) after which it will decrease the BUN concentration by up to 0.43 mg/dL BUN per mmol/L EDTA.
- Glutathione reduced will have no significant effect up to 1.7 mmol/L (52.2 mg/dL), after which it will increase the BUN concentration by up to 1.91 mg/dL BUN per mmol/L glutathione reduced. Blood glutathione (GSH) in human subjects is ~0.79-1.05 mmol/L. Long term oral glutathione reduced supplementation (250-1,000 mg/day administered for 6 months) increases glutathione plasma levels by ~0.2-8 µmol/L (~0.01-0.25 mg/dL). Short-term, oral intake of glutathione reduced does not affect plasma glutathione levels.
- β-Hydroxybutyrate will have no significant effect up to 17.2 mmol/L (216.9 mg/dL), after which it will decrease the BUN concentration by up to 0.11 mg/dL BUN per mmol/L hydroxybutyrate. The reference range for β-hydroxybutyrate in plasma is <0.4 to 0.5 mmol/L. β-hydroxybutyrate concentration over 3 mmol/L are indicative of ketoacidosis; in very severe diabetic ketoacidosis the concentration may exceed 25 mmol/L.
- Hydroxyurea will have no significant effect up to 1.3 mmol/L (9.9 mg/dL), after which it will increase the BUN concentration by up to 1.61 mg/dL BUN per mmol/L hydroxyurea. The recommended dose of hydroxyurea for patients range from 15 mg/kg/day to 30 mg/kg/day. A treatment dose of 2,000 mg/day (~30mg/kg) results in maximum plasma concentration of ~800µmol/L with oral administration and ~1 mmol/L with intravenous method.

- N-acetylcysteine will have no significant effect up to 9.2 mmol/L (150.1 mg/dL), after which it will increase the BUN concentration by up to 0.11 mg/dL BUN per mmol/L N- acetylcysteine. It has been reported that 1 mmol/L N-acetyl cysteine is therapeutically unattainable in plasma. The therapeutic level for N-acetyl cysteine is 0.3 mmol/L.
- Nithiodote will have no significant effect up to 4.1 mmol/L (64.8 mg/dL) after which it will decrease the BUN concentration by up to 0.41 mg/dL BUN per mmol/L Nithiodote. The expected peak sodium thiosulfate plasma concentration following a 12.5 g of Nithiodote is 16.7 mmol/L.

The following levels of exogenous interferences were tested and found to be clinically insignificant for BUN measurements: 1.324 mmol/L (20 mg/dL) acetaminophen, 2 mmol/L (21.6 mg/dL) Li acetoacetic acid, 3.62 mmol/L (65.2 mg/dL) acetyl salicylic acid, 1 mmol/L (5.349 mg/dL) ammonium chloride, 342 µmol/L (6.8 mg/dL) Na ascorbate, 37.5 mmol/L (386 mg/dL) Na bromide, 2.643 mmol/L (125.9 mg/dL) Na cefazolin, 1.46 mmol/L (96.6 mg/dL) Na ceftriaxone, 5.87 µmol/L (0.1 mg/dL) dopamine HCl, 86.8 mmol/L (400 mg/dL) ethanol, 50 µmol/L (4.46 mg/dL) (Flaxedil™) gallamine triethiodide, 28 mmol/L (0.5 g/dL) glucose, 2.55 mmol/L (156 mg/dL) oxidized glutathione, 5 mmol/L (38 mg/dL) glycolic acid, 20 U/mL heparin, 2.43 mmol/L (50 mg/dL) ibuprofen, (0.5%) 500 mg/dL intralipid, 1.3 mmol/L (19.4 mg/dL) Na iodide, 1 mmol/L (12 mg/dL) L-cysteine, 25 µmol/L (~0.5 mg/dL) L-Dopa, 3.2 mmol/L (13.5 mg/dL) lithium chloride, 6 mmol/L (210.8 mg/dL) Na metamizole, 2 mmol/L (90 mg/dL) methotrexate, 0.22 mmol/L (4 mg/dL) oxalate (K) monohydrate, 248 µmol/L (6.5 mg/dL) Na pentothal, 1 mmol/L (12.2 mg/dL) Na perchlorate, 4.34 mmol/L (69.5 mg/dL) Na salicylate, 1.72 mmol/L (16.7 mg/dL) K thiocyanate.

The following levels of endogenous interferences were tested and found to be clinically insignificant for BUN measurements: 342 µmol/L (28.8 mg/dL) bilirubin conjugated, 428 µmol/L (25 mg/dL) bilirubin unconjugated, 35 mmol/L bicarbonate, Hct 20% to 60% PCV, 6.6 mmol/L (74 mg/dL) lactate, pH 6.8 to 8, 3.5% to 10% total protein, 1.4 mmol/L (23.5 mg/dL) uric acid.

Clinically significant interfering substances for TCO_2 measurements are itemized below:

- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause significant decrease in TCO_2 results. For proper line-flushing procedures refer to CLSI H11-A4.
- Citrate will have no significant effect up to 11.8 mmol/L (347.0 mg/dL) after which it will increase the TCO_2 concentration by up to 0.24 mmol/L TCO_2 per mmol/L citrate.

- EDTA will have no significant effect up to 4.8 mmol/L (178.7 mg/dL) after which it will increase the TCO_2 concentration by up to 0.57 mmol/L TCO_2 per mmol/L EDTA.
- N-acetyl cysteine will have no significant effect up to 9.6 mmol/L (156.7 mg/dL) after which it will increase the TCO_2 concentration by up to 0.54 mmol/L TCO_2 per mmol/L N-acetyl cysteine. It has been reported that 1 mmol/L N-acetyl cysteine is therapeutically unattainable in plasma. The therapeutic level for N-acetyl cysteine is 0.3 mmol/L.

The following levels of exogenous interferences were tested and found to be clinically insignificant for TCO_2 measurements: 1.324 mmol/L (20 mg/dL) acetaminophen, 2 mmol/L (21.6 mg/dL) Li acetoacetic acid, 3.62 mmol/L (65.2 mg/dL) acetyl salicylic acid, 1 mmol/L (5.349 mg/dL) ammonium chloride, 342 µmol/L (6.8 mg/dL) Na ascorbate, 37.5 mmol/L (386 mg/dL) Na bromide, 2.643 mmol/L (125.9 mg/dL) Na cefazolin, 1.46 mmol/L (96.6 mg/dL) Na ceftriaxone, 5.87 µmol/L (0.1 mg/dL) dopamine HCl, 86.8 mmol/L (400 mg/dL) ethanol, 50 µmol/L (4.46 mg/dL) (Flaxedil™) gallamine triethiodide, 28 mmol/L (0.5 g/dL) glucose, 2.55 mmol/L (156 mg/dL) oxidized glutathione, 2.55 mM (78.4 mg/dL) reduced glutathione, 5 mmol/L (38 mg/dL) glycolic acid, 20 U/mL heparin, 2 mmol/L (15 mg/dL) hydroxyurea, 2.43 mmol/L (50 mg/dL) ibuprofen, (0.5%) 500 mg/dL intralipid, 1.3 mmol/L (19.5 mg/dL) Na iodide, 1 mmol/L (12 mg/dL) L-cysteine, 25 µmol/L (~0.5 mg/dL) L-Dopa, 3.2 mmol/L (13.5 mg/dL) lithium chloride, 6 mmol/L (210.8 mg/dL) Na metamizole, 2 mmol/L (90 mg/dL) methotrexate, 16.7 mmol/L (264 mg/dL) Nithiodote, 0.22 mmol/L (4 mg/dL) oxalate (K) monohydrate, 248 µmol/L (6.5 mg/dL) Na pentothal, 1 mmol/L (12.2 mg/dL) Na perchlorate, 4.34 mmol/L (69.5 mg/dL) Na salicylate, 1.72 mmol/L (16.7 mg/dL) K thiocyanate.

The following levels of endogenous interferences were tested and found to be clinically insignificant for TCO_2 measurements: 342 µmol/L (28.8 mg/dL) bilirubin conjugated, 428 µmol/L (25 mg/dL) bilirubin unconjugated, Hct 20% to 60% PCV, 20 mmol/L (252 mg/dL) β-hydroxybutyrate, 6.6 mmol/L (74 mg/dL) lactate, pH 6.8 to 8, 3.5% to 10% total protein, 1.4 mmol/L (23.5 mg/dL) uric acid.

5. Clinical Field Precision

The external precision study was conducted to evaluate the precision of the BUN and TCO_2 quantitation on the epoc System in the hands of the intended users. The study was evaluated based on CLSI guideline EP05-A3 at three different clinical sites using a different lot of epoc test card at each site. All testing was performed by existing or potential POC operators. Testing was comprised of three parts: 1) aqueous control precision using syringes, 2) whole blood precision using syringes, 3) whole blood precision using capillary tubes.

Clinical Field Precision with Aqueous Controls

Parameter	Aqueous Control Fluid					
	Level 1		Level 2		Level 3	
BUN [mg/dL]						
N	170		171		168	
Mean BUN [mg/dL]	52.1		17.7		7.1	
Repeatability (S_{WR} [SD], %CV)	1.06	2.0%	0.45	2.5%	0.24	3.4%
Between-day (SD, %CV)	0.94	1.8%	0.48	2.7%	0.03	0.5%
Between-site (SD, %CV)	0.60	1.2%	0.90	5.1%	0.10	1.4%
Total Reproducibility (S_T [SD], %CV)	1.54	3.0%	1.11	6.3%	0.26	3.7%
TCO_2 [mM]						
N	172		170		169	
Mean TCO_2 [mM]	15.9		19.7		30.4	
Repeatability (S_{WR} [SD], %CV)	0.44	2.8%	0.66	3.4%	0.58	1.9%
Between-day (SD, %CV)	0.16	1.0%	0.20	1.0%	0.76	2.5%
Between-site (SD, %CV)	0.18	1.1%	0.34	1.7%	0.42	1.4%
Total Reproducibility (S_T [SD], %CV)	0.50	3.1%	0.78	3.9%	1.05	3.4%

Clinical Field Precision with Whole Blood

Sample ID	Num. Runs	Num. of Operators	n	Avg	Min	Max	S_{WR}	%CV
BUN [mg/dL]								
Hi-Syringe	12	12	134	57.4	51.8	72.4	1.3	2.3%
Hi-Cap Tube	12	12	136	55.5	51.3	60.3	1.6	2.9%
NB-Syringe	12	12	136	17.3	12.5	35.3	0.7	4.1%
NB-Cap Tube	12	12	135	15.6	11.9	20.8	0.6	3.9%
Lo-Syringe	12	12	136	7.0	3.7	10.6	0.6	7.2%
Lo-Cap Tube	12	12	135	7.6	5.9	9.7	0.5	7.0%
TCO_2 [mM]								
Hi-Syringe	12	12	134	36.5	33.8	40.0	0.6	1.5%
Hi-Cap Tube	12	12	139	34.1	31.7	36.2	0.7	2.1%
NB-Syringe	12	12	136	27.5	22.3	30.9	0.4	1.4%
NB-Cap Tube	12	12	137	25.6	22.4	28.3	0.7	2.9%
Lo-Syringe	12	12	136	10.5	5.0	15.9	0.4	3.7%
Lo-Cap Tube	12	12	134	13.5	11.2	15.0	0.5	3.5%

Hi = High Level; NB = Normal Blood Range; Lo = Low Level

Precision was additionally assessed on duplicate epoc test results during the Method Comparison Studies. Over 430 patient tests were run in duplicate with approximately equal numbers of venous, arterial and capillary samples. Pooled pair-wise precision was estimated over three concentration ranges for BUN and two concentration ranges for TCO_2.

Parameter	**BUN [mg/dL]**			**TCO_2 [mM]**	
Range	<22	22-100	>100	≤40	>40
N	253	143	12	524	23
Average Reading	13.1	44.2	111.1	24.5	44.8
Pair Precision (SD)	0.6	1.2	1.6	0.6	1.0
%CV	4.6%	2.7%	1.4%	2.6%	2.2%

6. Method Comparison

Urea method comparison studies were performed at three clinical sites per CLSI EP09-A3. Venous, arterial and capillary blood samples for a total of over 140 results for each blood type were compared an IDMS-traceable plasma/serum-based laboratory system. Pooled results are shown below.

BUN [mg/dL]	**Roche Cobas 8000**
N	433
Sxx	0.5
Syy	0.9
Intercept	0.3
Slope	0.985
Syx	1.8
Xmin	3
Xmax	118
R	0.998
Mean Bias at 26 mg/dL	-0.1±0.2

TCO_2 method comparison studies were performed at three clinical sites. Venous, arterial and capillary patient samples for a total of over 150 results for each blood type were compared with a whole blood point-of-care system. Pooled results are shown below.

TCO_2 [mM]	**i-STAT-CHEM8+**
N	574
Sxx	0.68
Syy	0.64
Intercept	-0.8
Slope	1.039
Syx	1.52
Xmin	7
Xmax	49
R	0.974
Mean Bias at 20 mM	0.0 $\pm$ 0.2

7. Matrix Comparison: Anticoagulant

A method comparison approach was used to compare the epoc BUN and TCO_2 results in venous blood samples, collected from over 60 volunteer donors into evacuated tubes containing no additive, and further aliquoted into three (3) vacutainers containing no-additive, Li-heparin and Na-heparin to create 3-way matched samples. It was concluded from the analysis that there was no significant difference between BUN and TCO_2 results in Li-heparinized, Na-heparinized and non-anticoagulated blood samples on the epoc System.

CONCLUSION

The information provided in this pre-market notification demonstrates that the epoc BGEM Test Card and Blood Analysis System is substantially equivalent to the legally marketed predicate device for its intended use.