December 29, 2017

Instrumentation Laboratory Co.
Carol Marble
Regulatory Affairs Director
180 Hartwell Road
Bedford, MA 01730

Re: K173403
Trade/Device Name: GEM Premier 5000
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (pCO_2, pO2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, CEM, CGZ, GKF, GKR, GLY
Dated: October 30, 2017
Received: October 31, 2017

Dear Carol Marble:

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)*

k173403

Device Name

GEM Premier 5000

Indications for Use *(Describe)*

The GEM Premier 5000 is a portable critical care system for use by health care professionals to rapidly analyze heparinized whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of pH, pCO2, pO2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O2Hb, COHb, MetHb, HHb, sO2*) parameters from arterial, venous or capillary heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity.
*sO2 = ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin.
• pH, pCO2, and pO2 measurements in whole blood are used in the diagnosis and treatment of life-threatening acid-base disturbances.
• Electrolytes in the human body have multiple roles. Nearly all metabolic processes depend on or vary with electrolytes:
• Sodium (Na+) measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.
• Potassium (K+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.
• Ionized calcium (Ca++) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.
• Chloride (Cl-) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders, such as cystic fibrosis and diabetic acidosis.
• Hematocrit (Hct) measurements in whole blood of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).
• Glucose (Glu) measurement is used in the diagnosis, monitoring and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
• Lactate (Lac) measurement is used:
• to evaluate the acid-base status of patients suspected of having lactic acidosis;
• to monitor tissue hypoxia and strenuous physical exertion;
• in the diagnosis of hyperlactatemia.
• Total Bilirubin (tBili) measurement is used to aid in assessing the risk of kernicterus and hyperbilirubinemia in neonates.
• CO-Oximetry (tHb, COHb, MetHb, O2Hb, HHb, and sO2) evaluates the ability of the blood to carry oxygen by measuring total hemoglobin and determining the percentage of functional and dysfunctional hemoglobin species.
• Total Hemoglobin (tHb): Total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.
• COHb: Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin 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.

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)*

Device Name

GEM Premier 5000

Indications for Use *(Describe)*

• MetHb: Methemoglobin measurements are used to determine different conditions of methemoglobinemia.
• HHb: Deoxyhemoglobin, as a fraction of total hemoglobin, is used in combination with oxyhemoglobin to measure oxygen status.
• O2Hb: Oxyhemoglobin, as a fraction of total hemoglobin, is used in combination with deoxyhemoglobin to measure oxygen status.
• sO2: Oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin, is used to measure oxygen status.

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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Instrumentation Laboratory
A Werfen Company

k173403
510(k) Summary

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

Submitter's Information	Instrumentation Laboratory (IL) Co. 180 Hartwell Road Bedford, MA 01730, USA
Contact Person	Carol Marble, Regulatory Affairs Director Phone: 781-861-4467 Fax: 781-861-4207 Email: cmarble@ilww.com
Preparation Date	December 19, 2017
Device Trade Name	GEM Premier 5000

Regulatory Information				
Analyte	**Regulation Section**	**Regulatory Description**	**Class**	**Product Code**
pCO_2	862.1120	Blood Gases (pCO_2, pO_2) and Blood pH system	II	CHL
Potassium	862.1600	Potassium test system	II	CEM
Chloride	862.1170	Chloride test system	II	CGZ
Hematocrit	864.5600	Automated hematocrit instrument	II	GKF
Total Hemoglobin	864.5620	Automated hemoglobin system	II	GKR
	864.7500	Whole blood hemoglobin assays	II	GLY

Device Description
The GEM Premier 5000 system provides health care professionals with fast, accurate, quantitative measurements of pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb, sO_2*) parameters from arterial, venous or capillary heparinized whole blood in central laboratory or point-of-care clinical settings. *sO_2 = Ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin.

Purpose for Submission

The purpose of this submission is to expand capillary heparinized whole blood claims on the GEM Premier 5000 system to include the following analytes: pCO_2, potassium, chloride, hematocrit and total hemoglobin.

Note: The other measured analytes on the GEM Premier 5000 were previously FDA cleared for capillary claims under their respective 510(k): K160225, K160402, K160412 and K160415.

To support the expanded claims, a combination of improved sample handling instructions in the labeling to avoid pre-analytical error and cartridge EEPROM coefficient adjustments (for pCO_2, potassium and hematocrit) were implemented on the GEM Premier 5000.

Intended Use / Indications for Use

The GEM Premier 5000 is a portable critical care system for use by health care professionals to rapidly analyze heparinized whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb, sO_2*) parameters from arterial, venous or capillary heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity.

*sO_2 = ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin.

- pH, pCO_2, and pO_2 measurements in whole blood are used in the diagnosis and treatment of life-threatening acid-base disturbances.
- Electrolytes in the human body have multiple roles. Nearly all metabolic processes depend on or vary with electrolytes:
  - Sodium (Na^+) measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.
  - Potassium (K^+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.
  - Ionized calcium (Ca^{++}) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.
  - Chloride (Cl^-) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders, such as cystic fibrosis and diabetic acidosis.

Intended Use / Indications for Use (Cont.)

- Hematocrit (Hct) measurements in whole blood of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).
- Glucose (Glu) measurement is used in the diagnosis, monitoring and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
- Lactate (Lac) measurement is used:
  - to evaluate the acid-base status of patients suspected of having lactic acidosis;
  - to monitor tissue hypoxia and strenuous physical exertion;
  - in the diagnosis of hyperlactatemia.
- Total Bilirubin (tBili) measurement is used to aid in assessing the risk of kernicterus and hyperbilirubinemia in neonates.
- CO-Oximetry (tHb, COHb, MetHb, O_2Hb, HHb, and sO_2) evaluates the ability of the blood to carry oxygen by measuring total hemoglobin and determining the percentage of functional and dysfunctional hemoglobin species.
  - Total Hemoglobin (tHb): Total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.
  - COHb: Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.
  - MetHb: Methemoglobin measurements are used to determine different conditions of methemoglobinemia.
  - HHb: Deoxyhemoglobin, as a fraction of total hemoglobin, is used in combination with oxyhemoglobin to measure oxygen status.
  - O_2Hb: Oxyhemoglobin, as a fraction of total hemoglobin, is used in combination with deoxyhemoglobin to measure oxygen status.
  - sO_2: Oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin, is used to measure oxygen status.

Substantial Equivalence		
The following table compares the use of capillary heparinized whole blood samples with pCO_2, potassium, chloride, hematocrit and total hemoglobin on the GEM Premier 5000 to the predicate device, the GEM Premier 4000.		
Item	**Predicate Device**	**New Device**
Trade Name	GEM Premier 4000	GEM Premier 5000
510(k) No.	K133407	Pending
Manufacturer	Instrumentation Laboratory Co.	Instrumentation Laboratory Co.
Intended Use / Indications for Use	The GEM Premier 4000 is a portable critical care system for use by health care professionals to rapidly analyze whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb) parameters. Total bilirubin can also be quantitated from heparinized plasma samples when analyzed in the tBili/CO-Ox mode. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity. Total bilirubin measurements are used in the diagnosis and management of biliary tract obstructions, liver disease and various hemolytic diseases and disorders involving the metabolism of bilirubin. In neonates, the level of total bilirubin is used to aid in assessing the risk of kernicterus.	The GEM Premier 5000 is a portable critical care system for use by health care professionals to rapidly analyze heparinized whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb, sO_2*) parameters from arterial, venous or capillary heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity. *sO_2 = ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin. See previous pages for complete Intended Use/Indications for Use for the GEM Premier 5000.

Substantial Equivalence (Cont.)			
Item	**Predicate Device**		**Modified Device**
Trade Name	GEM Premier 4000	K133407	GEM Premier 5000
Intended Settings	Central Laboratory and Point-of-Care		Same
Sample Type	Heparinized whole blood (arterial, venous or capillary)		Same; expanding capillary claims to pCO_2, K^+, Cl^-, Hct and tHb with this 510(k)
Detection Method	**Analyte**	**GEM Premier 4000**	**GEM Premier 5000**
	pCO_2	Potentiometry	Same
	K^+	Potentiometry	Same
	Cl^-	Potentiometry	Same
	Hct	Conductivity	Same
	tHb	Spectrophotometry	Same
Sample Introduction	Aspiration		Same
PAK Shelf-Life Stability	Up to 180 days		Same
PAK Storage Temperature	15-25°C		Same
System Operating Temperature	12-32°C		Same
Operating System Software	Linux-based		Same
Calibration	2-point calibration		Same
Reportable Range	**Analyte**	**GEM Premier 4000**	**GEM Premier 5000**
	pCO_2	6 to 125 mmHg	6 to 125 mmHg
	K^+	0.2 to 19.0 mmol/L	1.0 to 19.0 mmol/L
	Cl^-	40 to 158 mmol/L	40 to 158 mmol/L
	Hct	15 to 72%	15 to 72%
	tHb	3.0 to 23.0 g/dL	3.0 to 23.0 g/dL

Performance Summary

Note: The linearity, limit of detection and analytical specificity performance for pCO_2, K^+, Cl^-, Hct and tHb on the GEM Premier 5000 were previously established under K160225, K160412 and K160415 for heparinized whole blood and these studies are also applicable for capillary heparinized whole blood. Consequently, studies performed were limited to precision and method comparison to support substantial equivalence for these analytes with capillary samples.

Internal Precision – Capillary Transfer Samples

In accordance with CLSI EP05-A3, an internal precision study was performed using five (5) different concentrations of whole blood per analyte, each run on three (3) GEM Premier 5000 analyzers per sample level for five (5) days, with one (1) run per day and eight (8) replicates measured per run per level (N=120 per analyte per level). Samples were transferred from syringe to a capillary device.

All results met specification.

Analyte	Level	Mean	N	Within Run SD	Within Run %CV
pCO_2 (mmHg)	1	9.9	120	0.5	5.1%
	2	34.5	120	0.6	1.9%
	3	49.0	120	0.5	1.1%
	4	68.9	120	1.6	2.3%
	5	108.9	120	2.4	2.2%
K^+ (mmol/L)	1	1.46	120	0.05	3.2%
	2	2.70	120	0.06	2.1%
	3	5.43	120	0.04	0.8%
	4	7.16	120	0.07	1.0%
	5	17.29	120	0.15	0.9%
Cl^- (mmol/L)	1	53.4	120	0.4	0.8%
	2	75.8	120	0.4	0.5%
	3	89.8	120	0.4	0.4%
	4	110.7	120	0.4	0.4%
	5	152.8	120	0.7	0.4%

Performance Summary (Cont.)

Internal Precision – Capillary Transfer Samples (Cont.):

Analyte	Level	Mean	N	Within Run SD	Within Run %CV
Hct (%)	1	19.3	120	0.6	2.9%
	2	32.8	120	0.6	1.9%
	3	44.7	120	0.6	1.3%
	4	55.0	120	0.8	1.5%
	5	63.7	120	1.3	2.0%
tHb (g/dL)	1	7.02	120	0.16	2.3%
	2	11.06	120	0.09	0.8%
	3	14.47	120	0.10	0.7%
	4	17.34	120	0.09	0.5%
	5	19.92	120	0.25	1.3%

Performance Summary (Cont.)

Internal Precision – Capillary Finger-stick Samples

An internal precision study was performed on a single GEM Premier 5000 in the IL Customer Simulation Laboratory (CSL), using finger-stick samples drawn and run by two (2) point-of-care (POC) operators brought on site for the study.

The study used twenty-eight (28) donor samples, collected into two (2) capillary tubes via capillary puncture. Each capillary tube was run in singlicate.

Results were analyzed separately for samples with mean within the fixed acceptance criteria range (SD) and those in the variable acceptance criteria range (%CV).

All results met specification.

Analyte	N	Mean	Within Sample SD	Within Sample %CV
pCO_2 (mmHg)	56	39	1.3	3.3
K^+ (mmol/L)	56	4.1	0.11	2.6
Cl^- (mmol/L)	56	106	0.3	0.3
Hct (%)	56	43	0.7	1.7
tHb (g/dL)	56	14.2	0.14	1.0

Performance Summary (Cont.)

External POC Precision – Capillary Transfer Samples

A precision study was performed on a GEM Premier 5000 at an external point-of-care (POC) site, using heparinized whole blood patient samples transferred from syringe to a capillary device and run by three (3) POC operators.

The study used a minimum of twenty (20) residual whole blood samples run over five (5) days. Each sample was run in triplicate.

Results were analyzed separately for samples with mean within the fixed acceptance criteria range (SD) and those in the variable acceptance criteria range (%CV).

All results met specification.

Analyte	N	Mean	Within Sample SD	Within Sample %CV
pCO_2 (mmHg)	63	42	0.9	2.0
	3	88	0.6	0.7
K^+ (mmol/L)	66	4.0	0.05	1.2
Cl^- (mmol/L)	66	107	0.5	0.5
Hct (%)	66	30	0.7	2.4
tHb (g/dL)	60	11.0	0.29	2.6

Point-of-Care (POC) Method Comparison

A method comparison study was conducted comparing the GEM Premier 5000 to the GEM Premier 4000 (predicate device) with native capillary finger-stick samples. The samples were collected via finger-stick by six (6) POC operators at an external POC site (minimum of 40 native capillary samples) and three (3) POC operators in the IL internal Customer Simulation Laboratory (CSL) (minimum of 80 native sample samples), and then run in singlicate on both the test and predicate instruments.

The observed biases at the medical decision levels are shown below:

Pooled Point-of-Care Site and CSL Data with Native Capillary Samples							
Analyte	**N**	**Range Min**	**Range Max**	**MDL**	**Bias at MDL**	**95% CI of Bias at MDL**	**TEa**
pCO_2 (mmHg)	130	26	50	35	1.0	1.0 to 2.0	± 5.0
				50	1.0	1.0 to 2.0	± 5.0
				70	1.4%	1.4% to 3.1%	± 8%
K^+ (mmol/L)	130	3.1	6.7	3.0	0.1	-0.03 to 0.19	± 0.5
				5.8	0.1	0.05 to 0.30	± 0.5
				7.5	1.3%	0.7% to 6.8%	± 7%
Cl^- (mmol/L)	129	90	111	90	-1.1%	-1.1% to 0.0%	± 5%
				112	-0.9%	-0.9% to 0.0%	± 5%
Hct (%)	130	24	51	21	-0.4	-1.3 to 0.5	± 4
				33	-0.3	-0.7 to 0.1	± 4
				56	-0.1	-0.7 to 0.5	± 4
tHb (g/dL)	131	6.9	17.3	7.0	-0.27	-0.43 to -0.12	± 0.7
				10.5	-0.17	-0.25 to -0.09	± 0.7
				18.0	0.05	-0.07 to 0.16	± 1.0

Performance Summary (Cont.)

Point-of-Care (POC) Method Comparison (Cont.)

The data from the native capillary samples (finger-stick samples) previously presented were pooled with contrived whole blood samples (< 10%) prepared internally to span the claimed reportable range.

The regression analysis is shown below for each analyte:

Pooled Point-of-Care Site and CSL Data with Additional Contrived Capillary Results					
Analyte	**N**	**Slope**	**Intercept**	**r**	**Sample Range**
pCO_2 (mmHg)	139	1.000	1.000	0.980	11 to 87
K^+ (mmol/L)	140	1.000	0.100	0.995	1.5 to 17.6
Cl^- (mmol/L)	141	1.000	-1.000	0.995	45 to 149
Hct (%)	136	1.003	-0.407	0.987	15 to 64
tHb (g/dL)	137	1.028	-0.470	0.994	4.5 to 20.5

Conclusion

Based on the substantial equivalence comparison and the results of the conducted performance evaluations, it was concluded that the performance of pCO_2, potassium, chloride, hematocrit and total hemoglobin with capillary samples on the GEM Premier 5000 is as safe and effective as on the predicate device.