August 20, 2021

Instrumentation Laboratory Co.
Gabriella Erdosy
Sr. Regulatory Affairs Manager
180 Hartwell Road
Bedford, Massachusetts 01730

Re: K203790
Trade/Device Name: GEM Premier 5000
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, CGZ, JFP, CGA, KHP, MQM, GKF, GHS, GKR, GLY
Dated: December 23, 2020
Received: December 28, 2020

Dear Gabriella Erdosy:

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 -S

Marianela Perez-Torres, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k203790

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.

• 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

K203790
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	Gabriella Erdosy Sr. Regulatory Affairs Manager Phone: 781-861-4571 Fax: 781-861-4207 Email: gerdosy@ilww.com

Preparation Date	August 18, 2021

Device Trade Name	GEM Premier 5000

Predicate Devices	GEM Premier 5000	K173403,K160415, K160402, K160225

Regulatory Information					
GEM Premier 5000					
Analyte	**Regulation Section**	**Regulatory Description**	**Class**	**Product Code**	**Panel**
pH, pCO_2, pO_2	862.1120	Blood Gases (pCO_2, pO_2) and Blood pH system	II	CHL	75
Sodium	862.1665	Sodium test system	II	JGS	
Potassium	862.1600	Potassium test system	II	CEM	
Chloride	862.1170	Chloride test system	II	CGZ	
Ionized Calcium	862.1145	Calcium test system	II	JFP	

Regulatory Information					
GEM Premier 5000					
Glucose	862.1345	Glucose test system	II	CGA	
Lactate	862.1450	Lactic acid test system	I	KHP	
Analyte	**Regulation Section**	**Regulatory Description**	**Class**	**Product Code**	**Panel**
Total Bilirubin	862.1113	Bilirubin (total and unbound) in the neonate test system	I (Reserved)	MQM	75
Hematocrit	864.5600	Automated hematocrit instrument	II	GKF	81
CO-Oximetry	864.7425	Carboxyhemoglobin assay	II	GHS	
	864.5620	Automated hemoglobin system	II	GKR	
	864.7500	Whole blood hemoglobin assays	II	GLY	

Device Description

The GEM Premier 5000 system provides fast, accurate, quantitative measurements of heparinized whole blood pH, *p*CO2, *p*O2, Na+, K+, Cl-, Ca++, glucose, lactate, Hct, total bilirubin and CO-Oximetry (tHb, O2Hb, COHb, MetHb, HHb, sO2) from arterial, venous or capillary samples.

Indications for Use / Intended 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.
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Indications for Use / Intended Use

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- 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.

Reason for Submission

This Special 510(k) is being submitted to upgrade the operating system from Fedora 17 Linux to WindRiver LTS 18 Linux for the GEM Premier 5000 Instrument. The operating system is being upgraded to accommodate long-term support of resolutions for common vulnerability exposures.

The submission meets the criteria for a Special 510(k) based on the following:

- The proposed change is submitted by the manufacturer legally authorized to market the existing device.
- Performance data is limited to Software Verification and Validation as the scope of this Special 510(k) is specific to an operating system upgrade from Fedora 17 Linux to WindRiver LTS 18 Linux.
- There is a well-established method to evaluate the change:
    - General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002
    - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005
    - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff, October 2, 2014
    - Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, September 2019
- The data can be reviewed in a summary or risk analysis format.

In addition, the changes in this submission do not introduce:

- Changes to indications for use or intended use
- Changes to the fundamental scientific technology
- Changes to operating principle
- Changes to labeled performance claims

Risk Management

The Risk Management was performed in compliance with EN ISO 14971:2012 (ISO 14971:2007) Medical Devices – Application of Risk Management to Medical Devices. A series of risk assessments were performed in order to identify and mitigate any potential risks associated to the design changes for the modified device.

Verification and Validation Summary

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

Cybersecurity Information
Cybersecurity assessments for the GEM Premier 5000 were performed as part of the Quality Management procedures for software validation and risk analysis activities. Vulnerabilities were identified, assessed and compensating controls were implemented within the software/system, to mitigate potential security threats, system vulnerabilities, viral attacks and safeguard against unauthorized access to patient data.

Comparison to Predicate		
Item	**Predicates (K173403, K160415, K160402, K160225)**	**Updated Device Subject of this Submission**
Similarities		
Trade Name	GEM Premier 5000	Same
Indications for Use	See above	Same
Intended User	Central Laboratory and Point-of-Care	Same
Blood Gas Measurement	Potentiometry: pH and pCO_2 Amperometry: pO_2	Same
Electrolyte Measurement	Potentiometry: Na^+, K^+, Cl^-, Ca^{++}	Same
Metabolite Measurement	Amperometry: Glucose and Lactate	Same
Hemoglobin Measurement	Spectrophotometry: tHb, O_2Hb, COHb, MetHb, HHb, sO_2	Same
Total Bilirubin	Spectrophotometry	Same
Hematocrit Measurement	Conductivity	Same
Sample Introduction	Aspiration	Same
Sampling Modes and Sample Volumes	• Normal Mode 150 µL • Micro Mode 65 µL • tBili/CO-Ox Mode 100 µL	Same
Test Principle	• Potentiometry: pH, pCO_2, Na^+, K^+, Ca^{++} • Amperometry: pO_2, Glu, Lac • Conductivity: Hematocrit	Same
Sample Type	Heparinized whole blood for all analytes	Same
Dimensions	• Height: 18.6 inches • Width: 13.0 inches • Depth: 16.4 inches	Same Same
Weight	• 45.4 pounds	Same
System Operating Temperature	• 12-32°C	Same
User Interface	Menu Driven Touch Screen	Same
Sample Introduction	Aspiration	Same
Differences		
Operating System Software	Fedora 17 Linux	Wind River LTS 18 Linux

Conclusion	The GEM Premier 5000, with the change in its operating system from Fedora 17 Linux to WindRiver LTS 18 Linux is substantially equivalent to the legally marketed predicate device last FDA cleared under K173403.