August 10, 2023

Instrumentation Laboratory Company
Gabriella Erdosy
Director of Regulatory Affairs
180 Hartwell Road
Bedford, Massachusetts 01730

Re: K223608
Trade/Device Name: GEM Premier 7000 with iQM$_3$
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, GKR, GHS, GLY
Dated: July 10, 2023
Received: July 11, 2023

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K223608

Device Name

GEM Premier 7000 with iQM3

Indications for Use *(Describe)*

The GEM Premier 7000 with iQM3 is a portable critical care system for use by health care professionals to rapidly analyze lithium 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 lithium 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

K223608: GEM Premier 7000 with IQM$_3$

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 Director of Regulatory Affairs Phone: 781-861-4571 Fax: 781-861-4207 Email: gerdosy@werfen.com

Preparation Date	August 10, 2023

Device Trade Name	GEM Premier 7000 with iQM$_3$

Predicate Device	GEM Premier 5000	K203790

Regulatory Information					
GEM Premier 7000 with iQM_3					
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	
Glucose	862.1345	Glucose test system	II	CGA	
Lactate	862.1450	Lactic acid test system	I*	KHP	
Total Bilirubin	862.1113	Bilirubin (total and unbound) in the neonate test system	I (Reserved)	MQM	
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	

* Meets limitations of exemptions per 21 CFR 862.9(c)(9)

Special Conditions for Use Statement

- For prescription use only.
- For clinical laboratory and point-of-care use.

Device Description	
The GEM Premier 7000 with iQM_3	
The GEM Premier 7000 with iQM_3 system provides health care professionals with quantitative measurements of lithium heparinized whole blood pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, Hct, total bilirubin and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb, sO_2*) from arterial, venous or capillary samples at the point of health care delivery in a clinical setting and in a central laboratory. *sO_2 = Ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin.	
Key Components	**Description**
Instrument	It employs a unique touch-sensitive color screen and a simple set of menus and buttons for user interaction. The analyzer guides operators through the sampling process with simple, clear messages and prompts.
PAK (Cartridge)	All required components for sample analysis are contained in the GEM PAK, including sensors, optical cell for CO-Oximetry and total bilirubin, sampler, pump tubing, distribution valve, waste container and Process Control Solutions. The GEM PAK is an entirely closed analytical system. The operator cannot introduce changes to the analytical process before or during the GEM PAK's use-life on board the instrument. The GEM PAK has flexible menus and test volume options to assist facilities in maximizing efficiency. The EEPROM on the GEM PAK includes all solution values and controls the analyte menu and number of tests. The setup of the instrument consists of inserting the GEM PAK into the instrument. The instrument will perform an automated GEM PAK start-up during which the following is performed: warm-up (15 minutes), sensor conditioning (10 minutes), Process Control Solution (PCS) performance (15 minutes), all of which take about 40 minutes. After GEM PAK start-up, Auto PAK Validation (APV) process is automatically completed: two completely independent solutions traceable to NIST standards, CLSI procedures or internal standards, containing two levels of concentration for each analyte (PC Solution D and E), are run by the analyzer to validate the integrity of the PC Solutions and the overall performance of the analytical system. Note: GEM PAKs that include tBili analyte will require the successful performance of CVP 5 tBili. Includes all necessary components for hemolysis detection, such as an acoustofluidic flow cell, an LED light source and an optical detector, for appropriate flagging of potassium measurements in whole blood samples without additional sample volume or sample processing steps.
Intelligent Quality Management (iQM3)	iQM3 is used as the quality control and assessment system for the GEM Premier 7000 system. iQM3 is an active quality process control program designed to provide continuous monitoring of the analytical process before, during and after sample measurement with real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, replacing the use of traditional external QC. iQM3 introduces hemolysis detection in whole blood samples, enhancing quality assessment in the pre-analytical phase of testing.

Indications for Use / Intended Use

The GEM Premier 7000 with iQM_3 is a portable critical care system for use by health care professionals to rapidly analyze lithium 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 lithium 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.
- 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;
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- Total Bilirubin (tBili) measurement is used to aid in assessing the risk of kernicterus and hyperbilirubinemia in neonates.
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  - 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.

Comparison to Predicate			
The GEM Premier 7000 with iQM_3 system is substantially equivalent in function and intended use to the following predicate device: • Predicate Device: GEM Premier 5000			
Item	**Predicate Device**		**New Device**
Trade Names	GEM Premier 5000	K203790	GEM Premier 7000 with iQM_3
Manufacturers	Instrumentation Laboratory Co.		Instrumentation Laboratory Co.
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.		Same

Indications for Use (Continued)	– 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, 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.	

Comparison to Predicate (Cont.)			
NOTE: The comparison on this page is to the predicate device, the GEM Premier 5000.			
Item	**Predicate Device**		**New Device**
Trade Names	GEM Premier 5000	K203790	GEM Premier 7000 with iQM_3
Similarities			
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	Same
	Micro Mode	65 µL	
	tBili/CO-Ox Mode	100 µL	
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

Comparison to Predicate (Cont.)			
NOTE: The comparison on this page is to the predicate device, the GEM Premier 5000.			
Item	**Predicate Device**		**New Device**
Trade Names	GEM Premier 5000	K203790	GEM Premier 7000 with iQM_3
Similarities (Continued)			
Sample Type	Heparinized whole blood (venous, arterial or capillary)		Same
Reportable Range	pH	7.00 to 7.92	Same
	pCO_2	6 to 125 mmHg	Same
	pO_2	6 to 690 mmHg	Same
	Na^+	100 to 180 mmol/L	Same
	K^+	1.0 to 19.0 mmol/L	Same
	Ca^{++}	0.11 to 4.25 mmol/L	Same
	Cl^-	40 to 158 mmol/L	Same
	Glucose	4 to 685 mg/dL	Same
	Lactate	0.3 to 17.0 mmol/L	Same
	Hematocrit	15 to 72%	Same
	tBili	2.0 to 40.0 mg/dL	Same
	tHb	3.0 to 23.0 g/dL	Same
	O_2Hb	0.7 to 100.0%	Same
	COHb	0.3 to 75.0%	Same
	MetHb	0.7 to 30.0%	Same
	HHb	1.0 to 100.0%	Same
	sO_2	0.7 to 100.0%	Same

Comparison to Predicate (Cont.)			
NOTE: The comparison on this page is to the predicate device, the GEM Premier 5000			
Item	**Predicate Device**		**New Device**
Trade Names	GEM Premier 5000	K203790	GEM Premier 7000 with iQM_3
Differences			
Instrument Dimensions	GEM Premier 5000 Instrument: • Height: 18.6 inches • Width: 13.0 inches • Depth: 16.4 inches • Weight: 45.4 pounds		GEM Premier 7000 with iQM_3 Instrument: • Height: 18.9 inches • Width: 12.9 inches • Depth: Same • Weight: 45.3 pounds
Cartridge (PAK) Dimensions	GEM Premier 5000 PAK (Cartridge): • Height: 6.75 inches • Width: 10 inches • Depth: 8 inches • Weight: 8.1 pounds		GEM Premier 7000 PAK with iQM_3 (Cartridge): • Height: 6.6 inches • Width: 10.2 inches • Depth: 7.6 inches • Weight: Same
Fluidic Pathway	The fluidic pathway directly connects Sensor Card and CO-Ox module		Addition of the new iQM quality check module between Sensor Card and CO-Ox module
Sample Fluidic Process	Micro Mode (65 µL)		Additional time (11s) for the new iQM quality check before analyte measurements
PAK (Reagent) Bags	Process Control Solution Bag (PCS) B		Addition of Heparin
Cartridge-Analyzer Interface	Cartridge fluidic components interface with hardware components on the analyzer		Modification to existing analyzer connection to support the iQM quality check module
Instrument	An analyzer capable of supporting the GEM Premier 5000 Cartridge (PAK)		An analyzer capable of supporting the GEM Premier 7000 with iQM_3 Cartridge (PAK)
PAK Compatibility	GEM Premier 5000 only		GEM Premier 7000 with iQM_3 only

Comparison to Predicate (Cont.)		
NOTE: The following table compares iQM2 on the GEM Premier 5000 to iQM3 on the GEM Premier 7000.		
Item	**Predicate Device**	**New Device**
Trade Names	iQM2 (Intelligent Quality Management 2)	iQM3 (Intelligent Quality Management 3)
Instrument	GEM Premier 5000	GEM Premier 7000 with iQM_3
510(k) No.	K203790	K223608
Quality Control Principle	Active quality process control program using a combination of internal Auto PAK Validation (APV) and one level of external Calibration Valuation Product (CVP 5), five internal Process Control Solutions (PCSs) Pattern Recognition (PR) software and IntraSpect sample integrity quality checks, all of which are designed to provide immediate error detection and automatic remedial action, replacing the use of traditional external quality controls.	Same
Error Detection Scheme	Multi-level checks for detecting cartridge errors. • System checks • Sensor/CO-Oximetry checks • IntraSpect checks • Pattern Recognition (PR checks) • Process Control Solution (PCS) Stability	Same except addition of Hemolysis detection. • Same, except addition of Hemolysis detection functionality • Same except the addition of Hemolysis Module Checks • Same • Same • Same • Hemolysis detection
Error Mitigation	Automatic error handling: • Performing special rinse cycle after detecting micro-clots and verifying the cartridge function after clot removal. • Permanently disabling failed sensor if its functionality could not be recovered. • Rejecting cartridge for process stability failure. • Alerting the user if interferences are detected in a sample. • Automatically documenting the failure and action taken. • IntraSpect	Same
Documentation	Automatic documentation: • Process Control Solutions delta charts. • Error reporting and corrective action report. • GEM CVP report.	Same

Comparison to Predicate (Cont.)		
NOTE: The following table compares internal Process Control (PC) Solutions in the GEM Premier 5000 PAK (cartridge) to internal Process Control (PC) Solutions in the GEM Premier 7000 with iQM_3 PAK (cartridge).		
Category	**Predicate Device**	**New Device**
Trade Names	Process Control (PC) Solutions	Process Control (PC) Solutions
Instrument	GEM Premier 5000	GEM Premier 7000 with iQM_3
510(k) No.	K203790	K223608
PC Solutions	• **PC Solution B** is the primary Process Control Solution measured at a minimum of every half hour or after every sample. Furthermore, Solution B is monitored every 30 seconds while residing in the sensor card between measurements. Further, PC Solution B is used as a reference blank for CO-Oximetry. • **PC Solution A** is measured at a minimum of every 4 hours. All sensor slope values are also measured and checked. Slope, which is an indicator of sensor sensitivity and drift, must be within allowable limits. PC Solution A also contains dyes that are used for checking functionality of the optical cell and the CO-Oximetry. • **PC Solution C** is measured at a minimum of once every 24 hours. PC Solution C is primarily used for measuring low-level oxygen; however, PC Solution C is also used to provide an additional measurement of pH, pCO_2 and K^+ sensor functionality. • **PC Solution D** is measured every 12 hours. PC Solution D provides additional measurement for all analytes including CO-Oximetry. Reference values for analytes in PC Solution D are assigned at time of manufacturing. The D sensor check starts after the successful completion of Auto PAK Validation (APV). • **PC Solution E** is measured every 12 hours. PC Solution E provides additional measurement for all analytes including CO-Oximetry. Reference values for analytes in PC Solution E are assigned at time of manufacturing. The E sensor check starts after the successful completion of Auto PAK Validation (APV).	• **PC Solution B** – Same, except the addition of Heparin • **PC Solution A** – Same • **PC Solution C** – Same • **PC Solution D** – Same • **PC Solution E** – Same

Performance Summary
Verification (Internal Method Comparison, Internal Whole Blood Precision, Hemolysis Interference on Potassium, Hemolysis Verification), Shelf-life and Use-life studies were performed to establish that the modifications introduced with the addition of the new iQM quality check (Hemolysis detection module) of the GEM Premier 7000 with IQM_3 do not impact the performance data represented in the Operators Manual. These studies followed recognized guidelines: • CLSI EP05-A3 • CLSI EP07, 3rd Ed • CLSI EP09c, 3rd Ed • CLSI EP25-A • CLSI EP37, 1st Ed All verification activities were performed in accordance to established plans and protocols and design control procedures. Testing verified that all acceptance criteria were met.

Conclusion	The technological and functional characteristics of the new GEM Premier 7000 with iQM_3 as described above are substantially equivalent to that of the predicate device GEM Premier 5000. The analytical study results demonstrate that the GEM Premier 7000 with iQM_3 is safe and effective for its intended purpose and equivalent in performance to the predicate device (K203790).