DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 14, 2016

INSTRUMENTATION LABORATORY CO.
CAROL MARBLE
REGULATORY AFFAIRS DIRECTOR
180 HARTWELL ROAD
BEDFORD MA 01730

Re: K160415
Trade/Device Name: GEM Premier 5000 (Measured Parameters: Hematocrit, Total Hemoglobin, Carboxyhemoglobin, Methemoglobin, Deoxyhemoglobin, Oxyhemoglobin, Oxygen Saturation)
Regulation Number: 21 CFR 864.5600
Regulation Name: Automated hematocrit instrument
Regulatory Class: Class II
Product Code: GKF, GHS, GKR, GLY
Dated: 12/7/2016
Received: 12/8/2016

Dear Ms. 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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Courtney H. Lias -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160415

Device Name
GEM Premier 5000 (Measured Parameters: Hematocrit, Total Hemoglobin, Carboxyhemoglobin, Methemoglobin, Deoxyhemoglobin, Oxyhemoglobin, Oxygen Saturation)

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 Hematocrit and Total Hemoglobin from venous and arterial heparinized whole blood, as well as quantitative measurements of O2Hb, COHb, MetHb, HHb, sO2 from venous, arterial and capillary heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's oxygen delivery capacity.

- 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).

- 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 oxygenation status.

- O2Hb: Oxyhemoglobin, as a fraction of total hemoglobin, is used in combination with deoxyhemoglobin to measure oxygenation status.

- sO2: Oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin, is used to measure oxygenation 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

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 8, 2016

Device Trade Name	GEM Premier 5000 (Measured Parameters: Hematocrit, Total Hemoglobin, Carboxyhemoglobin, Methemoglobin, Deoxyhemoglobin, Oxyhemoglobin, Oxygen Saturation)

Predicate Device	GEM Premier 4000	K133407

Regulatory Information					
GEM Premier 5000					
Analyte	**Regulation Section**	**Regulatory Description**	**Class**	**Product Code**	**Panel**
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 health care professionals in central laboratory or point-of-care clinical settings with fast, accurate, quantitative measurements of Hematocrit and Total Hemoglobin from venous and arterial heparinized whole blood, as well as quantitative measurements of O_2Hb, COHb, MetHb, HHb, sO_2 from venous, arterial and capillary heparinized whole blood. *sO_2 = Ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin.	
Key Components	**Description**
Analyzer	Employs a unique color touch 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.
GEM Premier 5000 PAK (disposable, multi-use GEM PAK)	Houses all required components necessary to operate the instrument once the cartridge is validated. These components include the sensors, CO-Ox optical cell, Process Control (PC) Solutions, sampler, pump tubing, distribution valve and waste bag. The GEM PAK has flexible menus and test volume options to assist facilities in maximizing efficiency. NOTE: The EEPROM on the GEM PAK includes all solution values and controls the analyte menu and number of tests. Step 1: After inserting the GEM PAK, the instrument will perform an automated PAK warm-up during which the sensors are hydrated and a variety of checks occur, all of which take about 40 minutes. During warm-up, the instrument requires no user intervention**.** Step 2: After GEM PAK warmup, Auto PAK Validation (APV) process is automatically completed: two completely independent solutions (PC Solution D and E) that are traceable to NIST standards, CLSI procedures or internal standards, containing two levels of concentration for each analyte, are run by the analyzer to validate the integrity of the PC Solutions and the overall performance of the analytical system. Step 3: After successful performance of APV, iQM2 manages the quality control process, replacing external quality controls.
Intelligent Quality Management 2 (iQM2)	iQM2 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. iQM2 is a statistical process control system that performs 5 types of continuous, quality checks to monitor the performance of the GEM PAK, sensors, CO-Ox, and reagents. These checks include System, Sensor, IntraSpect, Pattern Recognition and Stability Checks.

Indications for Use / Intended Use	
GEM Premier 5000	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 Hematocrit and Total Hemoglobin from venous and arterial heparinized whole blood, as well as quantitative measurements of O_2Hb, COHb, MetHb, HHb, sO_2 from venous, arterial and capillary heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's oxygen delivery capacity. • 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). • 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 oxygenation status. • O_2Hb: Oxyhemoglobin, as a fraction of total hemoglobin, is used in combination with deoxyhemoglobin to measure oxygenation status. • sO_2: Oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin, is used to measure oxygenation status.

Special Conditions for Use Statement

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

Substantial Equivalency		
The GEM Premier 5000 system is substantially equivalent in function and intended use to the following predicate device for Hematocrit and CO-Oximetry:		
Item	**Predicate Device**	**New Device**
Trade Name	GEM Premier 4000	GEM Premier 5000
510(k) No.	K133407	K160415
Manufacturer	Instrumentation Laboratory Co.	Instrumentation Laboratory Co.
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. NOTE: The GEM Premier 4000 also reports sO_2 results as a ratio result.	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 Hematocrit and Total Hemoglobin from venous and arterial heparinized whole blood, as well as quantitative measurements of O_2Hb, COHb, MetHb, HHb, sO_2 from venous, arterial and capillary heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's oxygen delivery capacity. • 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). • 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 oxygenation status. • O_2Hb: Oxyhemoglobin, as a fraction of total hemoglobin, is used in combination with deoxyhemoglobin to measure oxygenation status. • sO_2: Oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin, is used to measure oxygenation status.

Substantial Equivalency (Cont.)				
Item	**Predicate Device**		**New Device**	
Trade Names	GEM Premier 4000	K133407	GEM Premier 5000	K160415
Intended User	Central Laboratory and Point-of-Care		Same	
Sample Type	Heparinized Whole Blood		Hct, tHb	Arterial or venous heparinized whole blood
			O_2Hb, COHb, MetHb, HHb, sO_2	Arterial, venous or capillary heparinized whole blood
Hemoglobin Measurement	Spectrophotometry: tHb, O_2Hb, COHb, MetHb, HHb, sO_2		Same	
Hematocrit Measurement	Conductivity		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	
QC Material	CVP 1 and 2		PC Solution D and E (PAK Internal)	
	CVP 3 and 4		PC Solution D and E (PAK Internal)	
	CVP 5 tBili		Same; No Formulation Change	

<table>
<tr><th colspan="5">Substantial Equivalency (Cont.)</th></tr>
<tr><th>Item</th><th colspan="2">Predicate Device</th><th colspan="2">New Device</th></tr>
<tr><td>Trade Name</td><td colspan="2">GEM Premier 4000 K133407</td><td colspan="2">GEM Premier 5000 K160415</td></tr>
<tr><td>Instrument Dimensions</td><td colspan="2">GEM Premier 4000 Instrument:
• Height: 18 inches
• Width: 12 inches
• Depth: 15 inches
• Weight: 44 pounds</td><td colspan="2">GEM Premier 5000 Instrument:
• Height: 18.6 inches
• Width: 13.0 inches
• Depth: 16.4 inches
• Weight: 45.4 pounds</td></tr>
<tr><td>Cartridge (PAK) Dimensions</td><td colspan="2">GEM Premier 4000 Cartridge (PAK):
• Height: 6.75 inches
• Width: 10 inches
• Depth: 8 inches
• Weight: 8 pounds</td><td colspan="2">GEM Premier 5000 Cartridge (PAK):
• Height: 6.75 inches
• Width: 10 inches
• Depth: 8 inches
• Weight: 8.1 pounds</td></tr>
<tr><td rowspan="8">Reportable Range</td><td>Analyte</td><td>GEM Premier 4000</td><td colspan="2">GEM Premier 5000</td></tr>
<tr><td>Hematocrit</td><td>15 to 72%</td><td colspan="2">15 to 72%</td></tr>
<tr><td>tHb</td><td>3.0 to 23.0 g/dL</td><td colspan="2">3.0 to 23.0 g/dL</td></tr>
<tr><td>O_2Hb</td><td>0.0 to 98.0%</td><td colspan="2">0.7 to 100.0%</td></tr>
<tr><td>COHb</td><td>0.0 to 99.0%</td><td colspan="2">0.3 to 75.0%</td></tr>
<tr><td>MetHb</td><td>0.0 to 28.0%</td><td colspan="2">0.7 to 30.0%</td></tr>
<tr><td>HHb</td><td>0.0 to 96.0%</td><td colspan="2">1.0 to 100.0%</td></tr>
<tr><td>sO_2</td><td>0.0 to 100.0%</td><td colspan="2">0.7 to 100.0%</td></tr>
</table>

Performance Summary

Internal Precision Study – Aqueous Controls

In accordance with CLSI EP05-A3, an internal 20-day precision study was performed on the GEM Premier 5000, with GEM System Evaluator and GEM Hematocrit. Each of the control levels was run on three (3) GEM Premier 5000 analyzers for twenty (20) days, with two (2) runs per day and one (1) replicate measured per run per level (n=120). All results were within specification.

Material	Analyte	Level	Mean	N	Within Analyzer SD	Within Analyzer %CV	Total SD	Total %CV
GEM System Evaluator	tHb (g/dL)	Level 1	20.8	120	0.14	0.7%	0.16	0.8%
		Level 2	14.6	120	0.13	0.9%	0.18	1.2%
		Level 3	7.8	120	0.13	1.7%	0.16	2.1%
	O_2Hb (%)	Level 1	37.3	120	0.00	0.0%	0.00	0.0%
		Level 2	73.7	120	0.04	0.1%	0.05	0.1%
		Level 3	93.0	120	0.04	0.0%	0.05	0.1%
	COHb (%)	Level 1	31.7	120	0.03	0.1%	0.04	0.1%
		Level 2	16.8	120	0.05	0.3%	0.06	0.3%
		Level 3	3.1	120	0.07	2.3%	0.09	2.8%
	MetHb (%)	Level 1	8.3	120	0.05	0.6%	0.06	0.7%
		Level 2	2.6	120	0.06	2.5%	0.08	3.1%
		Level 3	Not Applicable					
	HHb (%)	Level 1	22.6	120	0.05	0.2%	0.05	0.2%
		Level 2	6.9	120	0.05	0.7%	0.06	0.9%
		Level 3	3.3	120	0.09	2.6%	0.11	3.2%
	sO_2 (%)	Level 1	62.2	120	0.05	0.1%	0.05	0.1%
		Level 2	91.4	120	0.06	0.1%	0.07	0.1%
		Level 3	96.6	120	0.09	0.1%	0.11	0.1%
GEM Hematocrit Evaluator	Hct (%)	Level 1	21	120	0.2	1.2%	0.3	1.3%
		Level 2	41	120	0.2	0.6%	0.2	0.6%
		Level 3	65	120	0.4	0.6%	0.4	0.6%

Performance Summary (Cont.)

Internal Precision Study – GEM PAK (Cartridge) Process Control Solutions D and E

In accordance with CLSI EP05-A3, an internal 20-day precision study was performed with the GEM PAK (cartridge) Process Control Solutions (PCS) D and E run on three (3) GEM Premier 5000 analyzers for twenty (20) days, with two (2) runs per day and one (1) replicate measured per run per level (N=120 per analyte/per level). All results were within specification.

Material	Analyte	Mean	N	Within Analyzer SD	Within Analyzer %CV
PCS D	Hct (%)	27	120	0.2	0.6%
PCS E		37	120	0.0	0.1%
PCS D	tHb (g/dL)	7.4	120	0.05	0.6%
PCS E		16.5	120	0.04	0.2%
PCS D	O_2Hb (%)	79.9	120	0.13	0.2%
PCS E		49.8	120	0.06	0.1%
PCS D	COHb (%)	4.0	120	0.11	2.7%
PCS E		10.1	120	0.04	0.4%
PCS D	MetHb (%)	3.9	120	0.12	3.0%
PCS E		8.0	120	0.05	0.6%
PCS D	HHb (%)	12.2	120	0.35	2.9%
PCS E		32.1	120	0.14	0.4%
PCS D	sO_2 (%)	86.8	120	0.35	0.4%
PCS E		60.8	120	0.13	0.2%

Performance Summary (Cont.)

Internal Precision Study – Whole Blood

In accordance with CLSI EP05-A3, an internal precision study was performed using four (4) or five (5) different concentrations of whole blood per analyte, each run on three (3) GEM Premier 5000 analyzers per sample mode for five (5) days, with one (1) run per day and eight (8) replicates measured per run per level (N=120 per analyte/per sample mode). All results were within specification.

Sample Modes and Volumes:

- Normal Mode 150 µL
- tBili/CO-Ox Mode 100 µL

NOTE: Capillary not claimed for Hct and tHb on the GEM Premier 5000.

Analyte	Mode	Level	Mean	N	Within Run SD	Within Run %CV	Total SD	Total %CV
Hct (%)	Normal Mode	1	18	120	0.3	1.9%	0.4	2.5%
		2	33	120	0.3	1.0%	0.6	1.9%
		3	45	120	0.5	1.0%	0.8	1.8%
		4	57	120	0.6	1.1%	1.0	1.8%
		5	65	120	0.7	1.1%	0.9	1.4%
tHb (g/dL)	Normal Mode	1	6.2	120	0.04	0.6%	0.07	1.1%
		2	11.2	120	0.04	0.4%	0.14	1.3%
		3	15.1	120	0.05	0.3%	0.20	1.3%
		4	18.8	120	0.06	0.3%	0.23	1.2%
		5	21.7	120	0.08	0.4%	0.23	1.1%

Performance Summary (Cont.)

Internal Precision Study – Whole Blood (Cont.)

Analyte	Mode	Level	Mean	N	Within Run SD	Within Run %CV	Total SD	Total %CV
O_2Hb (%)	Normal Mode	1	9.1	120	0.21	2.4%	0.22	2.4%
		2	38.4	120	0.26	0.7%	0.26	0.7%
		3	77.0	120	0.20	0.3%	0.21	0.3%
		4	90.6	120	0.21	0.2%	0.23	0.3%
		5	96.4	120	0.18	0.2%	0.20	0.2%
	tBili/CO-Ox Mode	1	8.7	120	0.20	2.3%	0.25	2.9%
		2	38.0	120	0.27	0.7%	0.29	0.8%
		3	76.5	120	0.23	0.3%	0.34	0.4%
		4	90.2	120	0.22	0.2%	0.33	0.4%
		5	96.0	120	0.21	0.2%	0.31	0.3%
COHb (%)	Normal Mode	1	1.6	120	0.14	8.6%	0.22	13.4%
		2	5.6	120	0.16	2.9%	0.21	3.7%
		3	15.3	120	0.17	1.1%	0.23	1.5%
		4	30.3	120	0.21	0.7%	0.26	0.9%
		5	64.3	120	0.26	0.4%	0.31	0.5%
	tBili/CO-Ox Mode	1	1.8	120	0.18	9.9%	0.29	15.6%
		2	5.8	120	0.16	2.7%	0.24	4.2%
		3	15.4	120	0.20	1.3%	0.26	1.7%
		4	30.4	120	0.23	0.8%	0.31	1.0%
		5	64.3	120	0.31	0.5%	0.46	0.7%
MetHb (%)	Normal Mode	1	5.0	120	0.17	3.4%	0.22	4.4%
		2	9.9	120	0.19	1.9%	0.21	2.1%
		3	14.5	120	0.27	1.9%	0.29	2.0%
		4	25.5	120	0.28	1.1%	0.32	1.2%
	tBili/CO-Ox Mode	1	5.1	120	0.16	3.2%	0.19	3.7%
		2	10.0	120	0.21	2.1%	0.23	2.2%
		3	14.8	120	0.34	2.3%	0.36	2.4%
		4	25.6	120	0.21	0.8%	0.21	0.8%

Performance Summary (Cont.)

Internal Precision Study – Whole Blood (Cont.)

Analyte	Mode	Level	Mean	N	Within Run SD	Within Run %CV	Total SD	Total %CV
HHb (%)	Normal Mode	1	6.6	120	0.23	3.5%	0.30	4.6%
		2	20.5	120	0.24	1.2%	0.42	2.1%
		3	59.9	120	0.29	0.5%	0.46	0.8%
		4	90.0	120	0.22	0.2%	0.32	0.4%
	tBili/CO-Ox Mode	1	6.8	120	0.26	3.8%	0.51	7.4%
		2	20.9	120	0.25	1.2%	0.48	2.3%
		3	60.2	120	0.29	0.5%	0.60	1.0%
		4	90.1	120	0.23	0.3%	0.53	0.6%
sO_2 (%)	Normal Mode	1	9.2	120	0.21	2.3%	0.21	2.3%
		2	39.0	120	0.27	0.7%	0.30	0.8%
		3	79.0	120	0.23	0.3%	0.37	0.5%
		4	93.2	120	0.24	0.3%	0.29	0.3%
		5	98.7	120	0.25	0.2%	0.39	0.4%
	tBili/CO-Ox Mode	1	8.8	120	0.19	2.2%	0.25	2.8%
		2	38.7	120	0.27	0.7%	0.36	0.9%
		3	78.6	120	0.24	0.3%	0.43	0.6%
		4	92.9	120	0.26	0.3%	0.50	0.5%
		5	98.5	120	0.27	0.3%	0.35	0.4%

Performance Summary (Cont.)

Reproducibility Study with Aqueous Controls – Point-of-Care (POC) Setting

In accordance with CLSI EP05-A3, a reproducibility study was performed at three (3) external clinical point-of-care (POC) sites. The studies were run by a total of nine (9) different operators on three (3) different GEM Premier 5000 instruments, using a single lot of GEM Premier 5000 PAKs (cartridges). Each site used the same lots of GEM System Evaluator (GSE) and GEM Hematocrit Evaluator (GHE), running each control level in triplicate, twice a day for 5 days, for a total of 30 replicates per level (N=90 pooled). All results at all sites were within specification.

Pooled Multi-Site POC Data																
Analyte	**Material/ Level**	**N**	**Insert Range**	**Target**	**SD/CV Spec**	**Mean**	**Repeatability**		**Between-Run**		**Between-Day**		**Between-Site**		**Reproducibility**	
							SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Hct (%)	GHE 1	90	19-23	21	2	21	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%
	GHE 2	90	38-44	41	2	41	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%
	GHE 3	90	62-70	66	2	66	0.3	0.4%	0.1	0.1%	0.2	0.4%	0.4	0.6%	0.6	0.9%
tHb (g/dL)	GSE 1	90	19.5-21.9	20.7	0.5	20.7	0.14	0.7%	0.00	0.0%	0.05	0.2%	0.07	0.3%	0.16	0.8%
	GSE 2	90	13.8-15.4	14.6	0.35	14.5	0.10	0.7%	0.00	0.0%	0.05	0.3%	0.07	0.5%	0.13	0.9%
	GSE 3	90	7.0-8.4	7.7	0.35	7.7	0.10	1.3%	0.02	0.3%	0.03	0.4%	0.01	0.1%	0.10	1.4%
O_2Hb (%)	GSE 1	90	36.3-40.3	38.3	1.5	37.3	0.01	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.01	0.0%
	GSE 2	90	72.6-76.6	74.6	1.5	73.7	0.04	0.0%	0.00	0.0%	0.00	0.0%	0.03	0.0%	0.05	0.1%
	GSE 3	90	92.0-96.0	94.0	1.5	93.0	0.03	0.0%	0.00	0.0%	0.02	0.0%	0.01	0.0%	0.04	0.0%

Performance Summary (Cont.)

Reproducibility Study with Aqueous Controls – Point-of-Care (POC) Setting (Cont.)

Pooled Multi-Site POC Data (Cont.)																
Analyte	**Material/ Level**	**N**	**Insert Range**	**Target**	**SD/CV Spec**	**Mean**	**Repeatability**		**Between-Run**		**Between-Day**		**Between-Site**		**Reproducibility**	
							SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
COHb (%)	GSE 1	90	28.7-32.7	30.7	1.0	31.7	0.04	0.1%	0.02	0.1%	0.00	0.0%	0.02	0.1%	0.05	0.2%
	GSE 2	90	13.5-17.5	15.5	1.0	16.8	0.04	0.2%	0.00	0.0%	0.01	0.1%	0.01	0.1%	0.04	0.3%
	GSE 3	90	0.0-4.0	2.0	1.0	3.2	0.06	1.9%	0.00	0.0%	0.03	0.8%	0.01	0.4%	0.07	2.1%
MetHb (%)	GSE 1	90	7.8-11.8	9.8	1.0	8.3	0.05	0.6%	0.00	0.0%	0.00	0.0%	0.02	0.3%	0.06	0.7%
	GSE 2	90	2.2-6.2	4.2	1.0	2.5	0.04	1.7%	0.02	0.6%	0.02	0.7%	0.04	1.5%	0.06	2.4%
	GSE 3	Not Applicable														
HHb (%)	GSE 1	90	19.2-23.2	21.2	1.5	22.6	0.04	0.2%	0.00	0.0%	0.01	0.0%	0.04	0.2%	0.06	0.2%
	GSE 2	90	3.7-7.7	5.7	1.5	6.9	0.05	0.7%	0.01	0.2%	0.00	0.0%	0.03	0.5%	0.06	0.8%
	GSE 3	90	0.0-4.0	2.0	1.5	3.4	0.06	1.9%	0.02	0.5%	0.03	0.8%	0.03	0.8%	0.08	2.3%
sO_2 (%)	GSE 1	90	NA	NA	1.5	62.2	0.04	0.1%	0.00	0.0%	0.01	0.0%	0.04	0.1%	0.06	0.1%
	GSE 2	90			1.5	91.4	0.05	0.1%	0.01	0.0%	0.00	0.0%	0.04	0.0%	0.07	0.1%
	GSE 3	90			1.5	96.5	0.06	0.1%	0.02	0.0%	0.03	0.0%	0.03	0.0%	0.08	0.1%

Performance Summary (Cont.)

External Precision – Whole Blood

To evaluate whole blood precision on the GEM Premier 5000 system in the central laboratory and point-of-care (POC) settings, whole blood patient samples were tested at 2 external central laboratories and 1 internal Customer Simulation Laboratory (CSL), as well as at 3 external POC locations. For the central laboratory setting, the studies were performed by 3 operators on 3 GEM Premier 5000 instruments using a single lot of GEM Premier 5000 PAK (cartridge). For the POC setting, the studies were performed by 11 operators on 3 GEM Premier 5000 instruments, using a single lot of GEM Premier 5000 PAK (cartridge). At least two whole blood specimens were analyzed in triplicate daily for 5 days in both normal mode (150 µL) for all analytes, micro mode (65 µL) for Hct, and tBili/CO-Ox mode (100 µL) mode for the CO-Ox fractions. At the internal Customer Simulation Laboratory (CSL), contrived whole blood specimens were analyzed in addition to native specimens in order to cover the low and high medical decision levels of each analyte.

The precision results are summarized below:

Analyte	Mode	Site	N	Mean	Within Sample SD
Hct (%)	Normal Mode	POC1	54	27	0.3
		POC2	42	26	0.6
		POC3	30	28	0.7
		POC-All	126	27	0.5
		CSL	36	44	0.5
		Lab1	30	28	0.4
		Lab2	30	35	0.5
		Lab-All	96	36	0.5

Performance Summary (Cont.)

External Precision – Whole Blood (Cont.)

Analyte	Mode	Site	N	Mean	Within Sample SD
tHb (g/dL)	Normal Mode	POC1	54	8.9	0.10
		POC2	42	9.4	0.15
		POC3	30	9.6	0.15
		POC-All	126	9.2	0.13
		CSL	33	13.5	0.05
		Lab1	30	9.5	0.07
		Lab2	30	11.5	0.05
		Lab-All	93	11.6	0.06
O_2Hb (%)	Normal Mode	POC1	54	86.5	0.57
		POC2	42	93.2	0.31
		POC3	30	94.2	0.48
		POC-All	126	90.6	0.48
		CSL	30	76.7	0.27
		Lab1	30	81.4	0.73
		Lab2	30	81.7	0.65
		Lab-All	90	79.9	0.59
O_2Hb (%)	tBili/ CO-Ox Mode	POC1	45	91.2	1.00
		POC2	39	88.5	0.49
		POC3	30	97.0	0.31
		POC-All	114	91.8	0.71
		CSL	30	77.2	0.30
		Lab1	30	74.6	0.49
		Lab2	30	87.6	0.96
		Lab-All	90	79.8	0.65

Performance Summary (Cont.)

External Precision – Whole Blood (Cont.)

Analyte	Mode	Site	N	Mean	Within Sample SD
COHb (%)	Normal Mode	POC1	54	2.6	0.31
		POC2	42	1.8	0.19
		POC3	30	1.7	0.19
		POC-All	126	2.1	0.25
		CSL	36	3.3	0.15
		Lab1	30	1.6	0.16
		Lab2	30	1.3	0.16
		Lab-All	96	2.2	0.16
	tBili/ CO-Ox Mode	POC1	45	2.6	0.32
		POC2	39	1.9	0.21
		POC3	30	1.6	0.20
		POC-All	114	2.1	0.26
		CSL	36	3.3	0.10
		Lab1	30	1.4	0.19
		Lab2	30	1.6	0.18
		Lab-All	96	2.2	0.16
MetHb (%)	Normal Mode	POC1	9	1.6	0.22
		POC2	36	1.2	0.16
		POC-All	45	1.3	0.17
	tBili/ CO-Ox Mode	POC1	21	1.3	0.25
		POC2	33	1.5	0.27
		POC-All	54	1.4	0.27

Performance Summary (Cont.)

External Precision – Whole Blood (Cont.)

Analyte	Mode	Site	N	Mean	Within Sample SD
HHb (%)	Normal Mode	POC1	24	23.1	0.84
		POC2	15	10.0	0.41
		POC3	15	6.7	0.53
		POC-All	54	13.3	0.66
		CSL	30	21.1	0.34
		Lab1	27	18.4	0.69
		Lab2	15	32.6	0.81
		Lab-All	72	24.0	0.60
	tBili/ CO-Ox Mode	POC1	15	15.4	1.63
		POC2	21	14.7	0.58
		POC-All	36	15.0	1.14
		CSL	30	20.5	0.30
		Lab1	24	29.2	1.32
		Lab2	21	14.9	0.60
		Lab-All	75	21.5	0.80
sO_2 (%)	Normal Mode	POC1	54	89.4	0.63
		POC2	42	96.0	0.28
		POC3	30	96.3	0.46
		POC-All	126	93.2	0.50
		CSL	30	78.5	0.34
		Lab1	30	83.0	0.70
		Lab2	30	83.3	0.61
		Lab-All	90	81.6	0.57
	tBili/ CO-Ox Mode	POC1	45	94.5	1.04
		POC2	39	91.5	0.53
		POC3	30	99.1	0.32
		POC-All	114	94.7	0.74
		CSL	30	79.1	0.30
		Lab1	30	76.2	0.55
		Lab2	30	89.4	1.06
		Lab-All	90	81.6	0.71

Performance Summary (Cont.)

LoB, LoD and LoQ

In accordance with CLSI EP17-A2, LoB, LoD and LoQ were established using three (3) lots of GEM Premier 5000 PAKs (cartridges).

Following are the combined data results for LoB, LoD and LoQ:

Analyte	LoB	LoD	LoQ
Hematocrit (%)	4	4	7
Total Hemoglobin (g/dL)	0.2	0.3	1.3
O_2Hb (%)	0.5	0.7	0.7
COHb (%)	0.1	0.3	0.3
MetHb (%)	0.4	0.7	0.7
HHb (%)	0.5	1.0	1.0

Linearity

In accordance with CLSI EP06-A, eight (8) or nine (9) levels per analyte were prepared by spiking or diluting whole blood to challenge the claimed reportable range for each parameter. Each blood level was analyzed in triplicate on three (3) GEM Premier 5000 test analyzers and results compared to reference analyzers or standard reference procedures (i.e. CNMetHb procedure - CLSI H15-A3 for tHb).

NOTE: Combined data from limit of quantitation (LOQ) and linearity studies were used to support lower limit of the claimed reportable range.

Analyte	# of Levels	N per Level	Slope	Intercept	R^2	Tested Range	Reportable Range
Hct (%)	9	9	0.970	1.904	0.998	7 to 82	15 to 72
tHb (g/dL)	9	9	1.015	0.130	0.999	2.1 to 27.0	3.0 to 23.0
O_2Hb (%)	8	9	1.002	0.918	1.000	0.3 to 99.3	0.7 to 100.0
COHb (%)*	8	9	1.016	1.532	1.000	7.4 to 98.5	0.3 to 75.0
	5	120	1.004	-0.109	1.000	-0.08 to 10.2	
MetHb (%)*	9	9	1.035	0.029	1.000	3.3 to 38.9	0.7 to 30.0
	5	120	0.988	-0.149	1.000	0.3 to 9.9	
HHb (%)	8	9	1.004	-0.384	1.000	-0.01 to 99.6	1.0 to 100.0

*Additional results at the low-end against the predicate device.

Performance Summary (Cont.)

Analytical Specificity

In accordance with EP07-A2, an interference study was conducted on the GEM Premier 5000.

The table below lists substances that were screen tested with no observed interference on hematocrit and CO-Oximetry results:

Substance	Concentration	Tested analytes with no observed interference
Bilirubin	20 mg/dL	tHb/Hb fractions and sO_2
Biliverdin	4 mg/dL	tHb/Hb fractions and sO_2
Evans Blue	10 mg/L	tHb/Hb fractions and sO_2
Fetal Hemoglobin	78%	tHb/Hb fractions and sO_2
Indocyanine Green	10 mg/L	tHb/Hb fractions and sO_2
Leukocytes	44.43 x 10^3/µL	Hematocrit
Methylene Blue	20 mg/L	tHb/Hb fractions and sO_2
Platelets	785.0 x 10^3/µL	Hematocrit
Sulfhemoglobin	10%	tHb/Hb fractions and sO_2
Turbidity (Intralipid)	1% or 2006 mg/dL	Hematocrit, tHb/Hb fractions and sO_2

The table below lists substances that demonstrated interference with hematocrit results causing a clinically significant error (TEa) and the concentration of the interfering substance, as well as the bias and its direction (positive / negative):

Interfering Substance	Affected Analyte	Analyte Concentration	Interfering Concentration Tested	Bias Observed (Mean)	Lowest Interfering Concentration with Analyte Impact	Bias Observed at the Lowest Concentration
Albumin	Hematocrit	30%	45.00 g/L	+4%	43.92 g/L	+4%
		62%	60.00 g/L	+5%	49.90 g/L	+4%

Note: For Hematocrit, all biases are expressed in absolute % (i.e. measured units, not %CV).

Performance Summary (Cont.)

Analytical Specificity (Cont.)

The table below lists substances that demonstrated interference with CO-Oximetry results causing a clinically significant error (TEa) and the concentration of the interfering substance, as well as the bias and its direction (positive / negative):

Interfering Substance	Affected Analyte	Analyte Concentration	Interfering Concentration Tested	Bias Observed (Mean)	Lowest Interfering Concentration with Analyte Impact	Bias Observed at the Lowest Concentration
Cyanocobalamin	tHb	10.2 g/dL	0.53 g/L*	+0.7 g/dL	0.45 g/L	<|0.7| g/dL
	O_2Hb	84.8%		-4.1%		-3.0%
	COHb	9.6%		-2.0%		<|2.0|%
	MetHb	5.0%		-2.0%		<|2.0|%
	HHb	<1.0%		<|3.0|%		<|3.0|%
	sO_2	99.3%		<|3.0|%		<|3.0|%
	tHb	19.0 g/dL	0.7 g/L*	No Interference Observed		
	O_2Hb	97.2%				
	COHb	1.5%				
	MetHb	<0.7%				
	HHb	<1.0%				
	sO_2	99.2%				
Cyano-methemoglobin	tHb	10.2 g/dL	4.0%*	<|0.7| g/dL	3.8%	<|0.7| g/dL
	O_2Hb	97.3%		<|3.0|%		<|3.0|%
	COHb	1.3%		<|2.0|%		<|2.0|%
	MetHb	0.7%		<|2.0|%		<|2.0|%
	HHb	<1.0%		+3.5%		+3.0%
	sO_2	99.3%		-3.1%		<|3.0|%
	tHb	20.1 g/dL	4.0%*	No Interference Observed		
	O_2Hb	97.5%				
	COHb	1.8%				
	MetHb	<0.7%				
	HHb	<1.0%				
	sO_2	99.9%				

*Results are flagged by iQM2 at the concentrations noted.

Note: For CO-Oximetry fractions, all biases are expressed in absolute % (i.e. measured units, not %CV).

Performance Summary (Cont.)

Analytical Specificity (Cont.)

Interfering Substance	Affected Analyte	Analyte Concentration	Interfering Concentration Tested	Bias Observed (Mean)	Lowest Interfering Concentration with Analyte Impact	Bias Observed at the Lowest Concentration
Hydroxocobalamin	tHb	9.5 g/dL	0.50 g/L*	+0.7 g/dL	0.34 g/L	<|0.7| g/dL
	O_2Hb	84.8%		-5.2%		<|3.0|%
	COHb	10.0%		<|2.0|%		-2.0%
	MetHb	4.5%		+2.6%		<|2.0|%
	HHb	<1.0%		-3.9%		<|3.0|%
	sO_2	99.3%		+3.5 %		<|3.0|%
	tHb	19.6 g/dL	1.00 g/L*	+0.8 g/dL	0.83 g/L	+0.7 g/dL
	O_2Hb	97.6%		-3.4%		<|3.0|%
	COHb	1.5%		<|2.0|%		<|2.0|%
	MetHb	<0.7%		<|2.0|%		<|2.0|%
	HHb	<1.0%		<|3.0|%		<|3.0|%
	sO_2	99.9%		<|3.0|%		<|3.0|%

*Results are flagged by iQM2 at the concentrations noted

Note: For CO-Oximetry fractions, all biases are expressed in absolute % (i.e. measured units, not %CV)

Performance Summary (Cont.)

Internal Method Comparison

In accordance with EP09-A3, an internal method comparison study was conducted using clinical samples to compare the GEM Premier 5000 to the GEM Premier 4000.

Samples were altered as needed to cover the medical decision levels. All parameter levels passed specification for all sample modes.

NOTE: Capillary not claimed for Hct and tHb on the GEM Premier 5000.

Analyte	N	Slope	Intercept	R^2	Medical Decision Level	Bias at Medical Decision Level
Hct (%)	376	1.013	-0.651	0.998	21	-0.4
					33	-0.2
					56	0.1
tHb (g/dL)	376	1.040	-0.144	0.998	7.0	0.14
					10.5	0.28
					18.0	0.58
O_2Hb (%)	373	0.998	0.700	1.000	90.0	0.54
COHb (%)	374	0.997	-0.349	1.000	3.0	-0.36
					10.0	-0.38
MetHb (%)	270	1.000	0.200	0.998	5.0	0.20
					10.0	0.20
HHb (%)	195	1.000	-0.426	0.999	6.0	-0.43
sO_2 (%)	373	0.995	0.783	0.999	90.0	0.31

Performance Summary (Cont.)

Whole Blood Performance at Medical Decision Levels

The data from the internal method comparison and precision studies were combined to assess the performance at medical decision levels.

Total Error was computed based on the following equation and the results were compared to the GEM Premier 5000 Total Error Specifications:

Total Error Observed = Bias + 2 * SD (or %CV)

Note: Previously shown bias and precision data were used in Total Error computations below.

Analyte	Medical Decision Level	Absolute Value of Bias at Medical Decision Level	2*(SD or %CV)	Total Error Observed Bias + 2*(SD or %CV)
Hct (%)	21	0.4	0.7	1.1
	33	0.2	0.7	0.9
	56	0.1	1.2	1.3
tHb (g/dL)	7.0	0.14	0.08	0.22
	10.5	0.28	0.08	0.36
	18.0	0.58	0.12	0.70
O_2Hb (%)	90.0	0.54	0.42	0.96
COHb (%)	3.0	0.36	0.28	0.64
	10.0	0.38	0.34	0.72
MetHb (%)	5.0	0.20	0.34	0.54
	10.0	0.20	0.38	0.58
HHb (%)	6.0	0.43	0.46	0.89
sO_2 (%)	90.0	0.31	0.48	0.79

Performance Summary (Cont.)

Reference Ranges

Analyte	Reference Range	Unit
Hct[1]	40-50 (male) and 37-47 (female**)**	%
tHb[1]	12.6 -17.4 (male) and 11.7 -16.1 (female)	g/dL
	126-174 (male) and 117-161 (female)	g/L
	7.8 -10.8 (male) and 7.3 -10.0 (female)	mmol/L
O_2Hb[2]	90.0 to 95.0	%
COHb[3-5]	<3.0 (nonsmoker) <10.0 (smokers)	%
MetHb[6]	0.0 to 1.5	%
HHb[7]	1.0 to 5.0	%
sO_2[1]	94 to 98	%

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Performance Summary (Cont.)

Clinical Testing

In accordance with EP09-A3, a method comparison study was conducted on the GEM Premier 5000 compared to the predicate device, the GEM Premier 4000, in the point-of-care (POC) setting using heparinized whole blood patient samples from the intended use population.

- Study Design:
  - Three (3) external point-of-care (POC) sites
  - One (1) internal Customer Simulation Laboratory (CSL) at IL, where three (3) intended POC users were brought on site to run the samples, allowing spiking to cover the reportable ranges.

The pooled results from the POC sites and the IL internal Customer Simulation Laboratory (CSL) for the Normal Mode (with samples collected in syringes) are presented below.

Pooled Point-of-Care Site and CSL Data - Normal Mode (with Syringe Samples)					
Analyte	**N**	**Slope**	**Intercept**	**r**	**Sample Range**
Hct (%)	490	1.003	-0.016	0.997	15 to 70
tHb (g/dL)	496	1.021	-0.055	0.998	3.1 to 22.8
O_2Hb (%)	496	1.003	0.338	0.999	12.2 to 99.0
COHb (%)	485	1.000	-0.198	0.998	0.3 to 73.8
MetHb (%)	297	1.000	-0.100	0.997	0.7 to 29.9
HHb (%)	258	1.007	-0.303	0.999	1.0 to 98.7
sO_2 (%)	494	0.998	0.355	0.999	12.3 to 100.0

Performance Summary (Cont.)

Clinical Testing (Cont.)

To support capillary claims, finger-stick samples were collected at an external POC site (N=52 native samples) and the IL internal Customer Simulation Laboratory (CSL) (N=100 native samples) with POC operators. The observed total error at the medical decision levels is shown below:

NOTE: Capillary not claimed for Hct and tHb on the GEM Premier 5000.

Pooled Point-of-Care Site and CSL Data with Native Capillary Samples Only							
Analyte	**N**	**Range Min**	**Range Max**	**MDL**	**Bias at MDL**	**95% CI of Bias at MDL**	**TEa**
O_2Hb (%)	152	84.9	97.4	90.0	1.19	0.48 to 1.89	± 3.0
COHb (%)	151	0.3	7.6	3.0	-0.31	-0.49 to -0.12	± 2.0
	180	0.3	73.8	10.0*	NA	NA	NA
				15.0*	NA	NA	NA
MetHb (%)	98	0.7	29.7	5.0*	NA	NA	NA
				10.0*	NA	NA	NA
HHb (%)	151	1.3	13.9	6.0	-0.56	-1.07 to -0.04	± 3.0
sO_2 (%)	152	86.0	99.1	90.0	1.20	-0.06 to 2.45	± 3.0

* There were an insufficient number of native samples to cover these MDLs.

Performance Summary (Cont.)

Clinical Testing (Cont.)

In addition, the data from the native capillary samples (finger-stick samples) previously presented were pooled with contrived capillary samples prepared internally. The regression analysis is shown below:

NOTE: Capillary not claimed for Hct and tHb on the GEM Premier 5000.

Pooled Point-of-Care Site and CSL Data with Additional Contrived Capillary Results					
Analyte	**N**	**Slope**	**Intercept**	**r**	**Sample Range**
O_2Hb (%)	182	1.000	0.802	0.997	13.7 to 98.6
COHb (%)	180	0.988	-0.269	0.999	0.3 to 73.8
MetHb (%)	98	1.000	-0.100	0.998	0.7 to 29.7
HHb (%)	181	1.001	-0.279	0.998	1.3 to 98.5
sO_2 (%)	180	0.994	0.930	0.997	13.9 to 100.0

Conclusion	The technological and functional characteristics of the new GEM Premier 5000 as described above are substantially equivalent to that of the predicate device (GEM Premier 4000) for hematocrit and CO-Oximetry. The analytical and clinical study results demonstrate that the GEM Premier 5000 is safe and effective for its intended purpose and equivalent in performance to the predicate device.