



K093623

JUN 18 2010

## 510(k) Summary

### Applicant Contact Information:

Applicant: Instrumentation Laboratory Co.  
Address: 180 Hartwell Road  
Bedford, MA 01730

Contact Person: Carol Marble, Regulatory Affairs Director  
Alternate Contact: Gabriella Erdosy, Senior Regulatory Affairs Officer  
Phone Number: 781-861-4467  
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Preparation Date: June 8, 2010

### Proprietary Names:

GEM<sup>®</sup> Premier 4000 with iQM<sup>®</sup> (Intelligent Quality Management)  
GEM<sup>®</sup> CVP 2 (Calibration Valuation Product) *with* CO-Ox  
GEM<sup>®</sup> CVP 5 (Calibration Valuation Product) tBili  
GEM<sup>®</sup> System Evaluator  
GEM<sup>®</sup> Hematocrit Evaluator

### Device Classification:

- Panel: Chemistry (75)
- Regulatory Sections: CFR 21 CFR 862.1110 Bilirubin (Total or Direct) Test System  
CFR 21 CFR 862.1113 Bilirubin (Total and Unbound) in the Neonate Test System  
CFR 21 CFR 862.1660 Quality Control Material (Assayed and Unassayed)  
CFR 21 CFR 864.8625 Hematocrit Control
- Classifications: Class II  
Class I, Reserved  
Class I  
Class II
- Product Codes: CIG  
MQM  
JJY  
GLK

### Predicate Devices:

K991417 ABL 735 Analyzer  
K061974 GEM Premier 4000 with iQM and CVP  
K860942 Quantimetrix Bilirubin Control

## Device Descriptions:

- **GEM Premier 4000 – Introductions / Modifications:**

- Addition of total bilirubin (tBili) measurement with whole blood and heparinized plasma on the GEM Premier 4000 performed using spectrophotometric multi-component analysis through the instrument's existing CO-Oximetry module. Following the electrochemical measurements for blood gases, electrolytes and metabolites, a portion of the sample is chemically hemolyzed and brought into an optical cell for the CO-Oximetry measurements and the additional total bilirubin measurement. There were no hardware or mechanical changes required, and no changes to the reagent cartridge (PAK) formulation or sensors. The measurement of total bilirubin was implemented through software.
- Expansion of the low-end reportable range for total hemoglobin (tHb) parameter from 5 g/dL to 3 g/dL through additional testing.
- Addition of a new 100 µL sample size for total bilirubin and CO-Oximetry mode only.
- Automation of fetal hemoglobin correction for CO-Oximetry. Previously the user would input the age of the patient to apply the correction. The new software applies the correction automatically based on the presence of fetal hemoglobin in the sample without user input.
- **GEM CVP 2 with CO-Ox:** This currently marketed external solution for the GEM Premier 4000 will also be value assigned for total bilirubin. No change in formulation.
- **GEM CVP 5 tBili:** An additional external solution for the GEM Premier 4000, containing purified human hemoglobin, stabilizers and biocide in a physiologically buffered matrix, is being introduced at another level of total bilirubin.
- **GEM System Evaluator:** Three-level aqueous buffered bicarbonate solution intended for use with the GEM Premier 4000 analyzer, containing inorganic salts and organic metabolites, dye and biocides; equilibrated with carbon dioxide and oxygen.
- **GEM Hematocrit Evaluator:** Three-level aqueous buffered bicarbonate solution intended for use with the GEM Premier 4000 analyzer, containing inorganic salts and biocides; equilibrated with carbon dioxide and oxygen.

#### Device Indications for Uses:

- **GEM Premier 4000 with iQM (Intelligent Quality Management)**
- **GEM CVP 2 (Calibration Valuation Product) with CO-Ox**
- **GEM CVP 5 (Calibration Valuation Product) tBili**

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,  $p\text{CO}_2$ ,  $p\text{O}_2$ , sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb,  $\text{O}_2\text{Hb}$ , 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.

Intelligent Quality Management (iQM) is used as the quality control and assessment system for the GEM Premier 4000 system. iQM is an active quality process control program designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, replacing the use of traditional external quality controls. Facilities should follow local, state and federal regulatory guidelines to ensure that a total quality management system is followed.

As part of this program, GEM CVP (Calibration Valuation Product) with CO-Ox, GEM CVP tBili and GEM CVP Hematocrit are external solutions intended to complete the calibration process and final accuracy assessment of the iQM cartridge calibration following warm-up. The reported values for GEM CVP (two levels for pH, blood gases, electrolytes, metabolites, total bilirubin, CO-Oximetry and hematocrit) must meet IL's specifications before the iQM cartridge can be used for patient sample measurements. Once the cartridge calibration is verified, the internal iQM program monitors the status of the system during the cartridge use life.

- **GEM System Evaluator** is a three level assayed quality control material intended for evaluating performance characteristics of pH,  $p\text{CO}_2$ ,  $p\text{O}_2$ , Electrolytes, Metabolites, Total Bilirubin (tBili) and CO-Oximetry on the GEM Premier 4000 analyzer.
- **GEM Hematocrit Evaluator** is a three-level assayed quality control material intended for evaluating performance characteristics of hematocrit on the GEM Premier 4000 analyzer.

**Statement of Technological Characteristics of the Device Compared to Predicate Devices:**

Testing supports that the GEM Premier 4000 when used for the measurement of total bilirubin (tBili) in conjunction with GEM CVP Level 2 *with* CO-Ox and GEM CVP 5 tBili and iQM is not materially different in intended use or performance from the ABL 735 Analyzer with traditional QC:

Characteristic	ABL 735 Analyzer (K991417)	GEM Premier 4000 with Total Bilirubin (tBili)
<b>Test Principle</b>	Spectrophotometry	Same
<b>Sample Type</b>	Whole Blood and Heparinized Plasma	Same
<b>Measured Parameter</b>	Total Bilirubin	Same
<b>Population</b>	Adults and Neonates	Same
<b>Tested Range</b>	0.0 to 23.5 mg/dL	0.3 to 40.0 mg/dL
<b>Controls</b>	External Traditional QC	CVP 2 <i>with</i> CO-Ox and CVP 5 tBili, in conjunction with iQM (Intelligent Quality Management)

Characteristic	GEM CVP 2 <i>with</i> CO-Ox (K061974)	GEM CVP 2 <i>with</i> CO-Ox (Total Bilirubin Claims Added)
<b>Intended Use</b>	External Calibration Valuation Product used to complete the calibration process of the GEM Premier 3000 and GEM Premier 4000 analyzers prior to use with patient samples.  NOTE: High pH, $pO_2$ , $Na^+$ , $K^+$ , $Cl^-$ , COHb, MetHb, HHb and low $pCO_2$ , $Ca^{++}$ , glucose, lactate, tHb and $O_2Hb$ values.	Same; except assigned with a high total bilirubin value
<b>Formulation</b>	Aqueous buffered bicarbonate solution containing inorganic salts and organic metabolites, stabilizer, dye and biocides; equilibrated with precise concentrations of carbon dioxide and oxygen	Same; no change in formulation
<b>Storage</b>	Unopened ampules are stable until the expiration date shown on the label when stored at 2-8°C, or up to 8 months at room temperature (15-25°C), providing storage does not exceed the expiration date. DO NOT FREEZE.	Same; no change in formulation

**Statement of Technological Characteristics of the Device Compared to Predicate Devices (Cont.):**

<b>Characteristic</b>	<b>Quantimetrix QC Bilirubin (K860942)</b>	<b>GEM CVP 5 tBili</b>
<b>Intended Use</b>	Intended as a means of monitoring various bilirubin assay methods to validate quantitation of patient samples. NOTE: Two total bilirubin levels (low and high).	External Calibration Valuation Product used to complete the calibration process of the GEM Premier 4000 analyzer prior to use with patient samples for total bilirubin (tBili) testing. NOTE: Low total bilirubin value.
<b>Formulation</b>	Prepared from purified bilirubin in a human protein base. Stabilizers and preservatives have been added.	Purified human hemoglobin, stabilizers and biocide in a physiologically buffered solution.
<b>Storage</b>	Store at 2-8°C	Store at 2-8°C

<b>Characteristic</b>	<b>GEM CVP 1 and 2 with CO-Ox (K061974)</b>	<b>GEM System Evaluator</b>
<b>Intended Use</b>	External Calibration Valuation Product used to complete the calibration process of the GEM Premier 3000 and GEM Premier 4000 analyzers prior to use with patient samples. NOTE: Two levels each for pH, pCO <sub>2</sub> , pO <sub>2</sub> , Electrolytes, Metabolites, tBili (CVP 2 only) and CO-Oximetry.	Three-level assayed quality control material for evaluating performance characteristics of pH, pCO <sub>2</sub> , pO <sub>2</sub> , Electrolytes, Metabolites, Total Bilirubin (tBili) and CO-Oximetry on the GEM Premier 4000 analyzer.
<b>Formulation</b>	Aqueous buffered bicarbonate solution	Same
<b>Stability</b>	2-8°C until expiration 15-25°C for 8 months	2-8°C until expiration 15-25°C for 4 months

<b>Characteristic</b>	<b>GEM CVP 3 and 4 Hematocrit (K061974)</b>	<b>GEM Hematocrit Evaluator</b>
<b>Intended Use</b>	External Calibration Valuation Product used to complete the calibration process of the GEM Premier 3000 and GEM Premier 4000 analyzers prior to use with patient samples. NOTE: Two levels for hematocrit.	Three-level assayed quality control material for evaluating performance characteristics of hematocrit on the GEM Premier 4000 analyzer.
<b>Formulation</b>	Aqueous buffered bicarbonate solution	Same
<b>Stability</b>	15-25°C until expiration	Same

**Substantial Equivalence:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems and quality controls already in commercial distribution. Equivalence is demonstrated through imprecision, method comparison, linearity, interference, sample matrix and stability studies, along with software development information.



Instrumentation Laboratory Company  
c/o Ms. Carol Marble  
Regulatory Affairs Director  
180 Hartwell Road  
Bedford, MA 01730

Food & Drug Administration  
10903 New Hampshire Avenue  
Building 66  
Silver Spring, MD 20993

JUN 18 2010

Re: k093623

Trade Name: GEM<sup>®</sup> Premier 4000 with iQM<sup>®</sup> (Intelligent Quality Management),  
GEM<sup>®</sup> CVP 2 (Calibration Valuation Product) with CO-Ox,  
GEM<sup>®</sup> CVP 5 (Calibration Valuation Product) tBili,  
GEM System Evaluator, GEM Hematocrit Evaluator

Regulation Number: 21 CFR §862.1110

Regulation Name: Bilirubin (Total or Direct) Test System

Regulatory Class: Class II

Product Codes: CIG, MQM, JJY, GLK

Dated: June 02, 2010

Received: June 03, 2010

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal line extending to the right.

Courtney C. Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K093623

Device Names: GEM® Premier 4000 with iQM® (Intelligent Quality Management)  
GEM® CVP 2 (Calibration Valuation Product) *with* CO-Ox  
GEM® CVP 5 (Calibration Valuation Product) tBili

### Indications for Use:

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Prescription Use              
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K093623



## Indications for Use Statement

510(k) Number (if known):     K093623    

Device Name:     GEM<sup>®</sup> System Evaluator  
                  GEM<sup>®</sup> Hematocrit Evaluator

### Indications for Use:

- GEM System Evaluator is a three-level assayed quality control material intended for evaluating performance characteristics of pH,  $p\text{CO}_2$ ,  $p\text{O}_2$ , Electrolytes, Metabolites, Total Bilirubin (tBili) and CO-Oximetry on the GEM Premier 4000 analyzer.
- GEM Hematocrit Evaluator is a three-level assayed quality control material for evaluating performance characteristics of hematocrit on the GEM Premier 4000 analyzer.

Prescription Use     ✓      
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

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