K061974

# 510(k) Summary
# GEM Premier 4000 with iQM and GEM CVP

**Submitted by:**

Instrumentation Laboratory Co.
113 Hartwell Avenue
Lexington, MA 02421

SEP 15 2006

**Contact Person:**

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**Summary Prepared:**

July 11, 2006

**Device Trade Names:**

- GEM® Premier 4000 with iQM® (Intelligent Quality Management)
- GEM CVP 1 and 2 (Calibration Valuation Product) *with* CO-Ox
- GEM CVP 3 and 4 (Calibration Valuation Product) Hematocrit

**Regulatory Information:**

- GEM Premier 4000 with iQM (Intelligent Quality Management)

| Description | CFR Section | Device Class | Product Code |
|---|---|---|---|
| Blood gases and blood pH | 862.1120 | Class II | CHL |
| Sodium test system | 862.1665 | Class II | JGS |
| Potassium test system | 862.1600 | Class II | CEM |
| Calcium test system | 862.1145 | Class II | JFP |
| Chloride test system | 862.1170 | Class II | CGZ |
| Glucose test system | 862.1345 | Class II | CGA |
| Lactic acid test system | 862.1450 | Class I | KHP |
| Automated hematocrit instrument | 864.5600 | Class II | GKF |
| Carboxyhemoglobin assay | 864.7425 | Class II | GHS |
| Automated hemoglobin system | 864.5620 | Class II | GKR |

- GEM CVP 1 and 2 (Calibration Valuation Product) *with* CO-Ox

| Description | CFR Section | Device Class | Product Code |
|---|---|---|---|
| Quality Control Material | 862.1660 | Class I | JJY |

- GEM CVP 3 and 4 (Calibration Valuation Product) Hematocrit

| Description | CFR Section | Device Class | Product Code |
|---|---|---|---|
| Hematocrit Control | 864.8625 | Class II | GLK |

# 510(k) Summary
# GEM Premier 4000 with iQM and GEM CVP

**Predicate Devices:**

| Description | 510(k) | Analytes |
|---|---|---|
| GEM 3000 with iQM and GEM CVP | K052121 | pH, blood gases, electrolytes (except chloride), glucose, lactate, hematocrit |
| IL Synthesis with traditional QC | K963800 | Chloride |
| IL 682 CO-Oximeter with traditional QC | K945677 | CO-Oximeter parameters |

**Device Description and 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, $pCO_2$, $pO_2$, $Na^+$, $K^+$, $Cl^-$, $Ca^{++}$, glucose, lactate, hematocrit and CO-Oximetry (tHb, $O_2Hb$, COHb, MetHb, HHb) parameters. 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.

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.

As part of this program, GEM CVP 1 and 2 (Calibration Valuation Product) *with* CO-Ox and GEM CVP 3 and 4 Hematocrit are external solutions intended to complete the calibration process and final accuracy assessment of the iQM cartridge calibration after initial warm-up. The reported values for the four levels of GEM CVP (two levels for pH, blood gases, electrolytes, metabolites and CO-Oximetry; two levels for hematocrit) must meet 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.

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

In-house and field site testing supports that the GEM Premier 4000 with iQM in conjunction with GEM CVP 1 and 2 *with* CO-Ox and GEM CVP 3 and 4 Hematocrit is not materially different from the above listed predicate devices in performance, safety and effectiveness or intended use. The operating principles for the different analytes are the same between the GEM Premier 4000 and the predicates:

| Operating Principle | Analyte(s) |
|---|---|
| Potentiometric | pH, $pCO_2$, $Na^+$, $K^+$, $Cl^-$, $Ca^{++}$ |
| Amperometric | $pO_2$, Glucose, Lactate |
| Conductivity | Hematocrit |
| Spectrophotometry | CO-Oximeter parameters |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.
113 Hartwell Avenue
Lexington, MA 02421

SEP 15 2006

Re: k061974
Trade/Device Name: GEM® Premier 4000 with iQM® (Intelligent Quality Management)
GEM CVP 1 and 2 (Calibration Valuation Product) with CO-Ox
GEM CVP 3 and 4 (Calibration Valuation Product) Hematocrit
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, JFP, CGZ, CGA, KHP, GKF, GHS, GKR, JJY, GLK, GLY
Dated: July 11, 2006
Received: July 12, 2006

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C Benson for

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number (if known):** k061974

**Device Name:** GEM® Premier 4000 with iQM® (Intelligent Quality Management)
GEM CVP 1 and 2 (Calibration Valuation Product) *with* CO-Ox
GEM CVP 3 and 4 (Calibration Valuation Product) Hematocrit

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Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

Division Sign-Off | Carol Benson

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional Format 1-2-96) k061974