Werfen Group | Instrumentation Laboratory

JAN 13 2014

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.

1. Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	180 Hartwell Road Bedford, MA 01730
Contact Person:	Carol Marble, Regulatory Affairs Director
Phone Number:	781-861-4467
Fax Number:	781-861-4207
E-mail:	cmarble@ilww.com
Preparation Date:	December 13, 2013

2. Proprietary Name:

GEM® Premier 4000

3. Regulatory Information:

- Common Name: Blood gases (pCO2 and pO2) and blood pH test system
- Classification Panel: Clinical Chemistry (75) and Hematology (81)
- Device Classifications, Classes and Product Codes are as follows:

Description	Classification	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
Whole blood hemoglobin assays	864.7500	Class II	GLY
Bilirubin (Total or Direct) Test System	862.1110	Class II	CIG
(Total and Unbound) in the Neonate Test System	862.1113	Class I, Reserved	MQM

4. Description of Device Modification:

Software V3.0.0 introduces the following new functionality to further improve the service and support of the GEM® Premier 4000:

- Remote desktop sharing to allow real-time sharing of the analyzer screen with IL service
- Remote software upgrades to facilitate deployment of future software versions
- Remote diagnostics to capture data for service diagnostic and trending purposes
- Remote LIS tracing to facilitate service diagnostics

NOTE: Software V3.0.0 also allows remote cartridge data (Copy IL Data) transfer. Copy IL Data is already available locally on the currently marketed GEM® Premier 4000 with GEMweb (stand-alone instruments) and GEMweb Plus data management system (server connected instruments) and is used to transmit data for service and complaint review.

5. Indications for Use (No Change from K112995):

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.

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.

6. **Substantial Equivalence:**

The GEM® Premier 4000 with remote features is substantially equivalent in Indications for Use, fundamental scientific technology and performance characteristics to the predicate:

GEM® Premier 4000 510(k): K112995

Similarities		
Characteristic	**Predicate Device**	**Modified Device**
Indications for Use	Identical Indications for Use	Same
Intended Use Site	Laboratory and point-of-care	Same
Performance Characteristics	Identical Performance Characteristics	Same
Test Principle	• Potentiometry: pH, pCO_2, Na+, K+, Cl-, Ca++ • Amperometry: pO_2, Glu, Lac • Conductivity: Hematocrit • Spectrophotometry: CO-Oximetry and tBili	Same
Sample Type	Whole blood for all analytes; Plasma for CO-Oximetry and tBili	Same
Dimensions	18 (H) x 12 (W) x 15 (D) inches	Same
Weight	44 pounds	Same
User Interface	Menu Driven Touch Screen	Same
Software Operating System	Fedora Core 9 (Linux)	Same
Sample Introduction	Aspiration	Same
Controls	In conjunction with iQM: • GEM CVP 1 and 2 *with* CO-Ox • GEM CVP 3 and 4 Hematocrit • GEM CVP 5 tBili	Same
Differences		
Characteristic	**Predicate Device**	**Modified Device**
Software	V2.3.0	V3.0.0
Remote Features	Not Available	• Remote desktop sharing to allow real-time interface between IL and customer • Remote software upgrades to facilitate future upgrades • Remote diagnostics to capture data for service diagnostic and trending purposes • Remote LIS tracing to facilitate service diagnostics

7. **Conclusion:**

For the implementation of the changes described above, design control principles (risk management, verification and validation) have been applied which support that the software release has no impact to the performance of the GEM® Premier 4000. Therefore, the performance data on record for the predicate device (K112995) still apply.

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

January 13, 2014

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

Re: K133407
Trade/Device Name: GEM Premier 4000
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases and blood pH
Regulatory Class: II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, KHP, GKF, GHS, GKR, GLY, CIG, MQM
Dated: December 13, 2013
Received: December 16, 2013

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 regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

k133407

Device Name

GEM® Premier 4000

Indications for Use *(Describe)*

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Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung-W.Chan -S

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