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

INSTRUMENTATION LABORATORY CO.
NIKITA MALLADI
REGULATORY AFFAIRS SPECIALIST II
180 HARTWELL ROAD
BEDFORD MA 01730

September 14, 2016

Re: K161818
Trade/Device Name: GEM Premier 3000
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, CHL, JGS, CEM, JFP, KHP, KFG
Dated: August 12, 2016
Received: August 15, 2016

Dear Nikita Malladi:

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 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" (21 CFR 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 yours,

Katherine Serrano -S

For: 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)*
k161818

Device Name
GEM Premier 3000

Indications for Use *(Describe)*
The GEM Premier 3000 is a portable system for use by health care professionals to rapidly analyze whole blood samples at the point of health care delivery in a clinical setting. The instrument provides quantitative measurements of whole blood pH, pCO2, pO2, Na+, K+, Ca++, Glucose, Lactate and Hct. These parameters along with derived parameters aid in the diagnosis of a patient's acid/base status, oxygen delivery capacity, and electrolyte and metabolite balance.

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	Nikita Malladi Regulatory Affairs Specialist II Phone: 781-674-3245 Fax: 781-861-4207 Email: nmalladi@ilww.com

Preparation Date	September 12, 2016

Device Trade Names	GEM Premier 3000

Predicate Device	GEM Premier 3000	K052121

Regulatory Information					
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	
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	
Hematocrit	864.5600	Automated hematocrit instrument	II	GKF	81

Device Description
The GEM Premier 3000 is designed as a portable system for use by health care professionals to rapidly analyze whole blood samples, in central laboratory or point-of-care clinical settings. The instrument provides both measured and calculated results for blood gases, hematocrit, electrolytes, glucose, and lactate.

Indications for Use / Intended Use
The GEM Premier 3000 is a portable system for use by health care professionals to rapidly analyze whole blood samples at the point of health care delivery in a clinical setting. The instrument provides quantitative measurements of whole blood pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Glucose, Lactate and Hct. These parameters along with derived parameters aid in the diagnosis of a patient's acid/base status, oxygen delivery capacity, and electrolyte and metabolite balance.

Reason for Submission
This Special 510(k) is being submitted to update the operating system from Linux Fedora Core 7 to Linux Fedora Core 21 for GEM Premier 3000 Instruments. The operating system is being updated to accommodate a change in the single-board computer due to obsolescence. The submission meets the criteria for a Special 510(k) based on the following: • No change in indications for use or intended use • No change in operating principle • No change to labeled performance claims • No change to data reduction software • No change to fluidic design • No change to GEM cartridges or CVP material

Comparison to Predicate		
Item	**Predicate (K052121)**	**Updated Device Subject of this Submission**
Similarities		
Trade Names	GEM Premier 3000	Same
Indications for Use	See above	Same
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^+, Ca^{++}	Same
Metabolite Measurement	Amperometry: Glucose and Lactate	Same
Hematocrit Measurement	Conductivity	Same
Sample Introduction	Aspiration	Same
Test Principle	• Potentiometry: pH, pCO_2, Na^+, K^+, Ca^{++} • Amperometry: pO_2, Glu, Lac • Conductivity: Hematocrit	Same
Sample Type	Whole blood for all analytes	Same
Dimensions	GEM3000 - 17 (H) x 12 (W) x 12 (D)”	Same Same
Weight	GEM3000 – 29.5 pounds	Same Same
User Interface	Menu Driven Touch Screen	Same
Sample Introduction	Aspiration	Same
Controls	In conjunction with iQM: GEM CVP 1, GEM CVP 2, GEM CVP 3 and GEM CVP 4	Same
Differences		
Software	GEM Premier 3000 V6.2.5	GEM Premier 3000 V6.3.0
Operating System Software	Linux Fedora Core 7	Linux Fedora Core 21
Single Board Computer	Win Enterprises 90140 Intel Pentium® M® / Celeron® M processor, 400MHz - ETX Module	Seco Q7-BT Rel. 2.0 Module with the Intel® Atom™ E3800

Declaration of Conformance to Design Controls	As required by the risk analysis, all verification and validation activities were performed and the results demonstrated that the predetermined acceptance criteria were met.
Verification and Validation Summary	Software verification and validation was performed according as defined in the GEM Premier 3000 V6.3.0 Project Software Verification Plan (Document No. L0024004020, See Section 32) and in accordance with the Software Design Verification Procedure. Software Validation was performed as defined in the GEM 3X00 Software Design and Development Plan for SBC Project (Document No. L0024003937, See Section 30). Testing verified that the SW V6.3.0 change meets requirements and that no new hazards have been introduced. This is documented in the GEM Premier 3000 V6.3.0 Software Verification report (Document No. L0024004116, See Section 33), and the GEM Premier 3000 V6.3.0 Software Validation Assessment (Document No. L0024005866, See Section 35).
Conclusion	Based on the shared indications for use, operating principle and performance claims, the GEM Premier 3000 with software V6.3.0 running on the Linux Fedora Core 21 operating system can be concluded to be substantially equivalent to the cleared and currently marketed predicate device, GEM Premier 3000.