K022158

SEP 1 0 2002

Section 3

GEM® Premier 3000: Introduction of iQM™ and GEM® CVP 510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

July 1, 2002

Name of the device:

GEM® Premier 3000: Introduction of iQM™ and GEM® CVP

Classification name(s):

75JJS	Controls for Blood-Gases (Assayed and Unassayed)	
75JJR	Electrolyte Controls (Assayed and Unassayed)	
862.1660	Quality Control Material (Assayed and Unassayed)	Class I
81GLK	*Hematocrit Control*	
864.8625	Hematology Quality Control Mixture	Class II

Identification of predicate device(s):

K010520	ContrIL® 9 (FDA cleared as a blood gas/electrolyte/metabolite quality control with the introduction of glucose and lactate on the GEM® Premier 3000)
K992834	GEM® critCheck (FDA cleared as a hematocrit quality control with the introduction of the GEM® Premier 3000)

Description of the device/intended use(s):

The GEM® Premier 3000 is a portable system for use by health care professionals to rapidly analyze whole blood samples that was originally cleared for the U.S. market by K992834, with glucose and lactate parameters added by K010520.

Intelligent Quality Management (iQM™) is being introduced on the GEM® Premier 3000 as 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 (Calibration Validation Product) is intended for the external verification of the iQM™ cartridge calibration after initial warm-up to ensure its integrity. The reported values for the four levels of GEM® CVP (two levels for pH, blood gases, electrolytes and metabolites; 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.

To ensure that a total quality management system is adhered to, laboratories should follow local, state and federal regulatory guidelines. As with any analytical device or computer software, there is always the potential for software failure. However, IL conducts rigorous testing and extensive software validation prior to releasing a software revision. If the user encounters a rare software error code, it should be reported to your local IL Technical Support Representative.

Section 3 (Cont.)
GEM® Premier 3000: Introduction of iQM™ and GEM® CVP 510(k) Summary (Summary of Safety and Effectiveness)

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

The use of Intelligent Quality Management (iQM™) in conjunction with GEM® CVP (Calibration Validation Product) on the GEM® Premier 3000 is not materially different from the use of external controls in performance, safety and effectiveness or intended use.

Summary of performance data:

GEM® CVP Precision

A precision study was performed on the GEM® Premier 3000 using the four levels of GEM® CVP (two levels for pH, blood gases, electrolytes and metabolites; two levels for hematocrit). Each level of the verification material was run in singlet once a day for 14 days (twice on Day 1) for a total of 15 replicates on each of 9 different GEM® Premier 3000 instruments (N=135).

	Parameter	Mean	Day-to-Day %CV (or SD)	Total %CV (or SD)
GEM® CVP Level 1	pH	7.200	0.005 (SD)	0.007 (SD)
	pCO_2 (mmHg)	70.8	1.39	1.63
	pO_2 (mmHg)	54.5	4.97	5.16
	Na^+ (mmol/L)	129.3	0.46	0.55
	K^+ (mmol/L)	2.90	0.25	0.70
	Ca^{++} (mmol/L)	1.493	0.95	1.26
	Glucose (mg/dL)	46.1	2.23	2.99
	Lactate (mmol/L)	0.93	4.73	4.87
GEM® CVP Level 2	pH	7.640	0.002 (SD)	0.003 (SD)
	pCO_2 (mmHg)	29.9	1.78	1.91
	pO_2 (mmHg)	148.2	1.33	1.93
	Na^+ (mmol/L)	158.7	0.44	0.56
	K^+ (mmol/L)	6.46	0.75	0.98
	Ca^{++} (mmol/L)	0.486	1.15	2.06
	Glucose (mg/dL)	192.8	1.67	1.78
	Lactate (mmol/L)	5.54	1.85	2.19
GEM® CVP Level 3	Hematocrit (%)	23.4	2.14	2.11
GEM® CVP Level 4	Hematocrit (%)	43.8	1.21	1.23

Summary of performance data (Cont.):

GEM® Premier 3000 with iQM™ Method Comparison

In addition, a method comparison study was performed to verify the performance of the GEM® Premier 3000 cartridge with iQM™ (Intelligent Quality Management). The method comparison data included arterial, venous, heart bypass and liver transplant blood samples from hospital patients using heparinized syringes. All samples were analyzed on the GEM® Premier 3000 with iQM™ versus an IL Synthesis as the reference instrument. The GEM® Premier 3000 with iQM™ was shown to be statistically similar to the reference instrument:

Analyte	N	Slope	Intercept	r	Sample Range
pH	281	1.0802	-0.5810	0.9917	7.129-7.559
pCO_2 (mmHg)	282	1.0674	-2.3800	0.9839	25.3-87.5
pO_2 (mmHg)	282	0.9715	6.9900	0.9988	26-489
Na^+ (mmol/L)	271	0.9801	2.9300	0.9584	119-148
K^+ (mmol/L)	271	0.9743	-0.0600	0.9871	3.2-7.4
Ca^{++} (mmol/L)	271	0.9196	0.1270	0.9590	0.82-1.40
Glucose (mg/dL)	283	1.0111	8.8700	0.9860	66-389
Lactate (mmol/L)	280	0.9323	0.1730	0.9958	0.49-16.67
Hct (%)	284	0.9983	-0.7999	0.9600	17-56

iQM™ (Intelligent Quality Management) Evaluation

- **Evaluation of Cartridge Malfunction Detection**

  Data from 79 GEM® Premier 3000 cartridges that demonstrated a QC failure during their cartridge use life were extensively analyzed. The Failure Pattern Recognition (FPR) checks were applied to these data to determine if iQM™ could detect any malfunction.

  The Failure Pattern Recognition (FPR) checks were able to detect malfunction in 74 out of 79 reported QC failures. In most cases, iQM™ would have flagged the failure immediately after the sample that caused the malfunction, while with conventional external controls, the user would only be aware of a problem when the external control is run again, which may be up to hours after the event occurred. Furthermore, no false positive flags were generated by the FPR checks in any of the 79 investigated cartridges.

  Resolution of 5 Unflagged QC Failures:

  For the 5 reported QC failures that iQM™ did not detect, there was no identifiable cartridge malfunction. All system parameters were within specifications. There were no error flags and no failure patterns. There were no unusual blood values for the parameter with reported QC failure and the customer did not report any concern about blood results. In all five cases, the reported QC failures were marginal and at one level only. It was concluded that the reported QC failures in these five cartridges could not represent a serious cartridge malfunction. The failures could be considered as a false positive QC failure.

Section 3 (Cont.)
GEM® Premier 3000: Introduction of iQM™ and GEM® CVP 510(k) Summary (Summary of Safety and Effectiveness)

Field Evaluation: External QC vs. iQM™

During an external field evaluation at a U.S. hospital, a side-by-side comparison was performed on a GEM® Premier 3000 using iQM™ versus two reference instruments, IL Synthesis and GEM® 3000 without iQM™ using traditional external quality controls. This study was conducted over a 3-week period with the external quality controls run during each day's shift: contrIL™ 9 on all three analyzers and GEM® critCheck on the GEM® analyzers only. Each GEM® instrument used a single 450 sample capacity cartridge (1 instrument with and 1 instrument without iQM™). A total number of 304 blood samples were tested.

During this field evaluation, there were no instances of external quality control failure on any instrument. However, the instruments experienced transient drift failures caused by interference as noted below:

- There were 4 instances of Benzalkonium exposure, which caused analyte failures on all three instruments.

- There were 8 instances of Thiopental Sodium* exposure, which caused analyte failures on both the GEM® instruments, with and without iQM™.

  *NOTE: The IL Synthesis is not affected by Thiopental Sodium.

In all of the above cases, the GEM® Premier 3000 using iQM™ successfully detected and flagged the failed analytes and identified the cause as interference. All three systems self-corrected by the next sample run and therefore, the interference went undetected by external quality controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 0 2002

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, MA 02421-3125

Re: k022158
Trade/Device Name: GEM® Premier 3000-iQM™ (Intelligent Quality Management) AND GEM® CVP (Calibration Validation Product)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA; GFS; JJY
Dated: July 1, 2002
Received: July 2, 2002

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 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 Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: GEM® Premier 3000 – iQM™ (Intelligent Quality Management) AND GEM® CVP (Calibration Validation Product)

Indications for Use:

The GEM® Premier 3000 is a portable system for use by health care professionals to rapidly analyze whole blood samples that was originally cleared for the U.S. market by K992834, with glucose and lactate parameters added by K010520.

Intelligent Quality Management (iQM™) is being introduced on the GEM® Premier 3000 as 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 (Calibration Validation Product) is intended for the external verification of the iQM™ cartridge calibration after initial warm-up to ensure its integrity. The reported values for the four levels of GEM® CVP (two levels for pH, blood gases, electrolytes and metabolites; 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.

To ensure that a total quality management system is adhered to, laboratories should follow local, state and federal regulatory guidelines. As with any analytical device or computer software, there is always the potential for software failure. However, IL conducts rigorous testing and extensive software validation prior to releasing a software revision. If the user encounters a rare software error code, it should be reported to your local IL Technical Support Representative.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022158

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.019)