NOV 24 1999

K992834

Section 3
GEM Premier 3000 - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

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Summary Prepared:

August 20, 1999

Name of the device:

GEM Premier 3000

Classification name(s):

75CHL	Electrode measurement, blood-gases (PCO_2, PO_2) and blood pH	
862.1120	Blood-Gases (PCO_2, PO_2) and blood pH test system	Class II
75JGS	Electrode, ion specific, sodium	
862.1665	Sodium test system	Class II
75CEM	Electrode, ion specific, potassium	
862.1600	Potassium test system	Class II
75JFO	Electrode, ion specific, calcium	
862.1145	Calcium test system	Class II
81GKF	Instrument, hematocrit, automated	
864.5600	Automated hematocrit instrument	Class II

Identification of predicate device(s):

K963800 IL Synthesis (except for hematocrit, which used manual spun hematocrit)

Description of the device/intended use(s):

The GEM Premier 3000, which is an upgraded version of the existing GEM Premier Plus (K961335), 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++, and Hct. These parameters along with derived parameters Base Excess, HCO_3, TCO_2 and sO_2 aid in the diagnosis of a patient's acid/base status, oxygen delivery capacity, and electrolyte and metabolite balance.

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

The GEM Premier 3000 is substantially equivalent in performance, intended use, safety and effectiveness to the IL Synthesis (predicate device) for the quantitative measurements of whole blood pH, pCO_2, pO_2, Na+, K+ and Ca++, and to manual spun hematocrit (predicate device) for Hct.

Summary of performance data:

Precision

Blood gas precision data were generated by using three levels of controls (GEM Check Plus) for pH, pCO_2, pO_2, Na+, K+, Ca++ and two levels of controls (GEM critCheck) for hematocrit. Control levels were run in replicates of 4 once a day for 14 days (twice on Day 1) for a total of 60 replicates on each of 7 different IL GEM 3000 instruments (total n=420). The table below shows the combined within run and total %CV of the seven instruments. **NOTE:** SD is used for pH since differences are so small that %CV would be misleading.

	Level 1			Level 2			Level 3		
Parameter	**Mean**	**Within Run %CV**	**Total %CV**	**Mean**	**Within Run %CV**	**Total %CV**	**Mean**	**Within Run %CV**	**Total %CV**
pH	7.0886	0.0066 (SD)	0.0180 (SD)	7.4276	0.0038 (SD)	0.0049 (SD)	7.6263	0.0040 (SD)	0.0082 (SD)
pCO_2 (mmHg)	66.02	1.95	2.82	36.37	2.37	2.45	16.79	2.89	3.76
pO_2 (mmHg)	64.42	2.14	2.77	103.69	0.86	1.63	155.65	0.82	1.20
Na+ (mmol/L)	118.55	0.63	0.98	135.51	0.42	0.72	152.61	0.63	1.18
K+ (mmol/L)	2.32	1.92	2.04	3.782	0.62	0.92	6.143	0.57	0.83
Ca++ (mmol/L)	0.753	2.16	2.68	1.071	0.94	1.50	1.387	0.88	1.30
Hct (%)	24.34	1.18	1.43	43.93	1.11	1.57	NA	NA	NA

Method Comparison

The method comparison data included arterial, venous, heart bypass and liver transplant blood samples from hospital patients using heparinized syringes and from healthy volunteers using heparinized vacutainer tubes. All samples were analyzed on the GEM Premier 3000 using an IL Synthesis as the predicate device with the exception of the hematocrit parameter, which used manual spun hematocrit as the predicate device. The GEM Premier 3000 was shown to be statistically similar to the predicate devices for the parameters listed below:

Parameter	**n**	**Slope**	**Intercept**	**r**	**Sample Range**
pH	128	1.0660	-0.4754	0.9931	7.10 – 7.60
pCO_2 (mmHg)	130	0.9721	2.1653	0.9935	24.6 – 99.6
pO_2 (mmHg)	128	0.9977	1.3552	0.9990	32 – 538
Na+ (mmol/L)	85	1.0181	-3.9552	0.9820	110 - 182
K+ (mmol/L)	84	0.9474	0.0736	0.9987	1.20 – 14.60
Ca++ (mmol/L)	80	0.9756	0.0202	0.9927	0.73 – 4.01
Hct (%)	117	1.0841	-3.4184	0.9548	16.0 – 54.0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 24 1999

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

Re: K992834
Trade Name: GEM Premier 3000
Regulatory Class: II
Product Code: CHL, JGS, CEM, JFO, GKF
Dated: November 11, 1999
Received: November 12, 1999

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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): K992834

Device Name: GEM Premier 3000

Indications for Use:

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Jean Cooper

(Division Sign-Off)
Division of Clin... Laboratory ...ices
510(k) Numbe... K992834

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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