

NOV 13 1996

K963800

SECTION 3
IL Synthesis™ - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

Betty Lane
Director, Regulatory Affairs
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02173
phone (617) 861-4182
fax (617) 861-4464

Contact Person:

Betty Lane
phone (617) 861-4182

Summary Prepared:

September 20, 1996

Name of the device:

IL Synthesis™

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
75JFØf	Electrode, ion specific, calcium	
862.1145	Calcium test system	Class II
75CGZ	Electrode, ion specific, chloride	
862.1170	Chloride test system	Class II
75LFR	Glucose dehydrogenase, glucose	
862.1345	Glucose test system	Class II
75CEM	Electrode, ion specific, potassium	
862.1600	Potassium test system	Class II
862.1665	Sodium test system	Class II

Classification name(s) (Cont.):

75JJE	Analyzer, chemistry (photometric, discrete), for clinical use	
862.2160	Discrete photometric chemistry analyzer for clinical use	Class I
75JJQ	Colorimeter, photometer, spectrophotometer for clinical use	
862.2300	Colorimeter, photometer or spectrophotometer for clinical use	Class I
91JKS	Spectral absorb, curve, oxyhemoglobin, carboxyhemoglobin, carbon-monoxide	
862.3220	Carbon monoxide test system	Class I
81GKF	Instrument, hematocrit, automated	
864.5600	Automated hematocrit instrument	Class II
81GKR	System, hemoglobin, automated	
864.5620	Automated hemoglobin system	Class II
81GHS	Assay, carboxyhemoglobin	
864.7425	Carboxyhemoglobin assay	Class II
81GLY	Oximeter to measure hemoglobin	
864.7500	Whole blood hemoglobin assays	Class II
862.1150	Calibrator	Class II
862.1660	Quality control material (assayed and unassayed)	Class I
864.8625	Hematology quality control mixture	Class II

Identification of predicate device(s):

IL 1400 BGElectrolyte Analyzer	K890827/A
IL 1430 BGElectrolyte Analyzer	K935069/S2
IL BGGE Blood Gas with Glucose Analyzer	K955793
IL 682 CO-Oximeter	K945677/S2
Radiometer ICA2 Ionized Calcium Analyzer	K801848

Description of the device/intended use(s):

The IL Synthesis is a family of fully automatic, microprocessor controlled, blood gas, electrolytes, glucose, hematocrit and co-oximeter analyzers. Its technology combines that of the IL BGElectrolytes Analyzer (IL 1400/1430) and the IL BGGE Blood Gas with Glucose Analyzer (IL 1660) with an integrated co-oximeter module. The IL Synthesis will be available in several different configurations of blood gas, electrolytes, co-oximeter, and glucose.

The intended use, methodology, concentration levels, working range and analytical results of the IL Synthesis are substantially equivalent to the predicate devices: IL BGElectrolytes Analyzer (IL 1400/1430), IL BGGE Blood Gas with Glucose Analyzer (IL 1660) and the ICA2 Ionized Calcium Analyzer.

The IL Synthesis (hardware, software, and reagents) is for the quantitative *in vitro* diagnostic determination of pH, pCO₂ (partial pressure of carbon dioxide), pO₂ (partial pressure of oxygen), sodium (Na⁺), potassium (K⁺), calcium (Ca⁺⁺), chloride (Cl⁻), glucose (Glu), and Hematocrit (conductivity) in whole blood or pCO₂ (partial pressure of carbon dioxide), pO₂ (partial pressure of oxygen) in expired gases by direct ion selective electrode (ISE) potentiometry. Sodium and potassium results are used to monitor electrolyte balance. Note that the number of electrodes is limited and any given instrument will only contain two of the three functions: calcium (Ca⁺⁺), chloride (Cl⁻) and Glucose (Glu).

The IL Synthesis (hardware, software, and reagents) also permits the quantitative *in vitro* diagnostic determination of five forms of hemoglobin in whole blood samples, total hemoglobin (tHb), oxyhemoglobin (%O₂Hb), carboxyhemoglobin (%COHb), methemoglobin (MetHb) and reduced hemoglobin, also called deoxyhemoglobin (%RHb) and will also calculate the following parameters: oxygen content of hemoglobin (O₂ct), oxygen binding capacity (O₂ cap) and oxygen saturation (sO₂m).

The IL Synthesis is designed for laboratory use to provide both measured and calculated results for blood gases, electrolytes, substrates, and co-oximeter parameters on blood and gas samples.

Statement of how the Technological Characteristics of the Device compare to the Predicate device:

The IL Synthesis uses the same technological characteristics as the predicate devices, IL BGElectrolytes Analyzer (IL 1400/1430), the BGGE Blood gas with Glucose Analyzer, and uses newer co-oximetry technology than the IL 682 CO-Oximeter. The IL Synthesis is substantially equivalent in performance, intended use, safety and effectiveness to the predicate devices: IL BGElectrolytes Analyzer (Cl), the IL BGGE Blood Gas with Glucose Analyzer (pH, pO₂, pCO₂, Na, K, Glu, Hct), Radiometer ICA2 Ionized Calcium Analyzer (Ca), and the IL 682 CO-Oximeter (co-ox).

Summary of performance data:

**BLOOD GAS
BETWEEN DAY IMPRECISION
USING contrIL PLUS and HCT CHECK QC MATERIAL**

Parameter	Level	n	INSTRUMENT 1			INSTRUMENT 2			INSTRUMENT 3		
			mean	SD	%CV	mean	SD	%CV	mean	SD	%CV
pH	1	60	7.597	0.141	0.19	7.596	0.015	0.02	7.596	0.0146	0.19
	2	60	7.418	0.006	0.08	7.418	0.007	0.09	7.418	0.0056	0.08
	3	60	7.138	0.006	0.08	7.137	0.006	0.09	7.138	0.0053	0.07
pCO ₂ (mmHg)	1	60	20.63	0.32	1.57	20.54	0.37	1.81	19.75	0.30	1.53
	2	60	37.51	0.30	0.81	37.52	0.46	1.23	37.18	0.14	0.37
	3	60	64.21	0.83	1.29	65.30	0.58	0.89	66.25	0.37	0.56
pO ₂ (mmHg)	1	60	146.6	0.83	0.57	145.6	0.81	0.56	145.9	0.89	0.61
	2	60	88.4	1.51	1.84	87.0	1.37	1.58	87.2	1.21	1.39
	3	60	51.3	1.65	2.02	50.3	1.90	3.79	51.27	1.75	3.41
Na (mmol/L)	1	60	114.8	0.70	0.61	118.6	0.58	0.49	116.9	0.65	0.77
	2	60	137.0	0.85	0.62	140.8	0.92	0.65	138.5	0.67	0.48
	3	60	159.1	2.26	1.42	162.4	2.07	1.28	159.5	1.89	1.18
K (mmol/L)	1	60	2.58	0.027	1.05	2.55	0.052	2.05	2.59	0.0242	0.93
	2	60	4.38	0.060	1.37	4.35	0.052	1.20	4.40	0.0495	1.13
	3	60	6.09	0.099	1.62	6.13	0.139	2.27	6.11	0.0722	1.18
Ca (mmol/L)	1	60	0.625	0.011	1.82	0.628	0.0095	1.51	N/A	N/A	N/A
	2	60	1.03	0.029	2.84	1.025	0.0257	2.51	N/A	N/A	N/A
	3	60	1.57	0.018	1.14	1.555	0.0146	0.94	N/A	N/A	N/A
Cl (mmol/L)	1	60	85.8	3.44	4.01	N/A	N/A	N/A	86.9	3.48	3.50
	2	60	108.9	1.23	1.13	N/A	N/A	N/A	109.6	1.13	1.03
	3	60	137.1	0.73	0.53	N/A	N/A	N/A	137.0	0.79	0.58
Gluc (mg/dL)	1	60	N/A	N/A	N/A	59.67	1.72	2.88	62.08	1.10	1.31
	2	60	N/A	N/A	N/A	84.75	3.24	3.83	86.56	1.09	1.26
	3	60	N/A	N/A	N/A	237.2	8.62	3.63	216.2	8.03	3.72
Hct (%)	Low	12	36.1	0.29	0.80	37.7	0.49	1.31	36.8	0.39	1.06
	High	12	63.7	0.89	1.39	65.0	00.0	00.0	64.9	0.51	0.79

Between day imprecision results were generated by using three levels of ContrIL Plus. For pH, pCO₂, pO₂, Na and K, samples were run in replicates of 5 once a day for 12 days for a total of 60 replicates on each of three IL Synthesis instruments. For calcium, chloride and glucose, samples were run in replicates of 5 once a day for 12 days for a total of 60 replicates on each of two IL Synthesis instruments. For hematocrit, two levels of Hct CHECK were run for 12 days for a total of 12 replicates on each of 3 instruments. The data were collected during in-house studies.

N/A = Not available. The IL Synthesis can be configured with any two of Ca⁺⁺, Cl⁻, and Glu.

Summary of performance data (continued):

CO-OX
BETWEEN DAY IMPRECISION
USING DYE-BASED CONTROLS

Parameter	Level	n	INSTRUMENT 1			INSTRUMENT 2			INSTRUMENT 3		
			mean	SD	%CV	mean	SD	%CV	mean	SD	%CV
tHb (mg/dL)	1	15	7.04	0.38	5.42	7.05	0.14	1.92	6.98	0.13	1.85
	2	15	13.78	0.65	4.68	13.82	0.35	2.55	13.52	0.18	1.33
	3	15	17.69	0.91	5.12	17.86	0.55	3.10	17.15	0.12	0.70
O ₂ Hb (%)	1	15	45.26	0.16	0.34	44.86	0.10	0.22	44.90	0.09	0.20
	2	15	93.56	0.08	0.08	93.54	0.08	0.08	93.66	0.08	0.08
	3	15	64.75	0.22	0.35	64.78	0.12	0.18	64.85	0.20	0.31
COHb (%)	1	15	53.73	0.15	0.28	54.15	0.08	0.14	54.13	0.09	0.18
	2	15	3.94	0.04	1.04	3.99	0.04	0.92	3.99	0.04	0.94
	3	15	34.71	0.22	0.63	34.72	0.09	0.27	34.70	0.20	0.57
MetHb (%)	1	15	0.50	0.00	0.00	0.473	0.04	8.62	0.413	0.04	8.83
	2	15	1.99	0.04	1.84	1.88	0.06	3.07	1.78	0.09	4.79
	3	15	0.50	0.00	0.00	0.50	0.00	0.00	0.46	0.04	9.72

Within run imprecision results were generated by using three levels of dye-based controls. For each parameter, samples were run in replicates of 5 once a day for 3 days for a total of 15 replicates on each of three IL Synthesis instruments. The data were collected during in-house studies.