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SECTION 3

**ILab 600 Clinical Chemistry System - 510(k) SUMMARY
(Summary of Safety and Effectiveness)**

Submitted by:

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Summary prepared:

February 26, 1998

Name of the device:

ILab 600 Clinical Chemistry System

Classification name(s):

CFR Ref.	Description	Class
862.2300 (75JJQ	Colorimeter, photometer or spectrophotometer for clinical use Colorimeter, photometer, spectrophotometer for clinical use)	I
862.2500 (75JJI	Enzyme analyzer for clinical use Analyzer, enzyme, for clinical use)	I
862.1020	Acid phosphatase (total or prostatic) test system	II
862.1030	Alanine amino transferase (ALT/SGPT) test system	I
862.1035	Albumin test system	II
862.1050	Alkaline phosphatase or isoenzymes test system	II
862.1070	Amylase test system	II
862.1100	Aspartate amino transferase (AST/SGOT) test system	II
862.1110	Bilirubin (total or direct) test system	II
862.1145	Calcium test system	II
862.1150	Calibrator	II
862.1160	Bicarbonate/carbon dioxide test system	II
862.1170	Chloride (total) test system	I
862.1175	Cholesterol	I
862.1210	Creatine test system	II
862.1215	Creatine phosphokinase/creatin kinase or isoenzymes test system	II

Classification name(s) (Continued)

CFR Ref.	Description	Class
862.1225	Creatinine test system	II
862.1345	Glucose test system	I
862.1360	Gamma-glutamyl transpeptidase and isoenzymes test system	I
862.1410	Iron (non-heme) test system	I
862.1440	Lactate dehydrogenase test system	II
862.1465	Lipase test system	I
862.1495	Magnesium test system	I
862.1580	Phosphorus (inorganic) test system	I
862.1600	Potassium test system	II
862.1635	Total protein test system	II
862.1660	Quality control material (assayed and unassayed)	I
862.1665	Sodium test system	II
862.1705	Triglyceride test system	I
862.1770	Urea nitrogen test system	I
862.1775	Uric acid test system	I
862.3240	Cholinesterase test system	I

Identification of predicate device(s):

K932467	ILab 900/1800 Clinical Chemistry System
K943595	ILab 900/1800 Clinical Chemistry System – Urine Claims Added
K943366	IL Test Acid Phosphatase
K952646	IL Test CK-MB
K943367	IL Test Cholinesterase
K952647	IL Test Lipase

Description of the device/intended use(s):

The ILab 600 is an automated, random access clinical chemistry analyzer which uses analytical techniques (photometry and potentiometry) for the *in vitro* quantitation of analytes found in physiological fluids such as serum, plasma, urine and cerebrospinal fluid. The results of the measurements are used as medical diagnostic tools.

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

The ILab 600 uses the same technology as the ILab 900 and is substantially equivalent in performance, intended use, safety and effectiveness. The ILab 600 and ILab 900 maintain the same reagent temperature, use the same reagent formulations and the same applications (proportional volumes). The ISE module on the ILab 600 is also very similar to that of the ILab 900 (predicate device); the same electrodes and solutions are utilized as is the same type of reaction mechanism.

Main differences:	<u>ILab 600</u>	<u>ILab 900</u>
• Throughput	Medium (400 tests/hour)	High (600 tests/hour)
• Optical Path Length	5 mm	6 mm
• Operating System	Windows NT	In-house Developed
• Reagent Volume	20-400 µL	50-600 µL

Summary of performance data:

Method Comparison Studies

In method comparison studies evaluating serum samples, the ILab 600 and the ILab 900 (predicate device) were shown to be statistically similar for the tests listed below.

IL Test	Units	n	Range	Slope	Intercept	r
Acid Phosp., Non-Prostatic	U/L	97	0.3-27.6	0.867	0.38	0.986
Acid Phosp., Total	U/L	94	0.4-33.4	0.957	0.197	0.996
Albumin	g/dL	98	2.9-5.5	1.047	-0.183	0.985
Alkaline Phosphatase	U/L	108	24-623	1.052	5.94	0.999
ALT/GPT	U/L	109	2-2557	1.006	-1.4	0.999
Amylase	U/L	110	25-377	1.040	0.1	0.997
AST/GOT	U/L	115	14-2377	1.065	0.1	0.998
Bilirubin, Direct	mg/dL	100	0.03-15.19	0.989	-0.029	0.999
Bilirubin, Total	mg/dL	99	0.02-26.52	0.955	0.034	0.999
Calcium	mg/dL	98	6.5-15.6	1.040	-0.028	0.990
Cholesterol	mg/dL	117	40-944	1.005	2.334	0.997
Cholinesterase	U/L	107	2166-12692	1.002	195.4	0.990
CK/CPK	U/L	103	18-3759	0.933	6.72	0.998
CK-MB	U/L	110	0.6-237.2	1.003	-1.4	0.997
Creatinine	mg/dL	99	0.8-7.1	1.029	0.147	0.998
Glucose Hexokinase	mg/dL	113	60-457	1.017	0.358	0.997
Glucose Oxidase	mg/dL	137	51-393	0.944	7.92	0.997
γ -GT	U/L	122	4-497	1.052	1.2	0.999
Iron	μ g/dL	97	10-253	1.040	2.37	0.998
LD-L/LDH-L	U/L	95	45-404	0.997	3.56	0.992
Lipase	U/L	64	8-2719	0.972	-1.7	0.999
Magnesium	mg/dL	103	1.60-8.24	0.988	0.01	0.994
Phosphorus	mg/dL	100	2.5-11.3	0.976	0.06	0.998
TCO2	mmol/L	102	10-36	1.079	-1.43	0.987
Total Protein	g/dL	98	4.6-8.8	0.966	0.16	0.992
Triglycerides	mg/dL	96	37-1039	0.978	1.414	0.999
Urea Nitrogen	mg/dL	119	7.0-68.0	1.007	-0.015	0.998
Uric Acid	mg/dL	99	1.9-15.9	0.963	0.11	0.995
ISE Chloride	mmol/L	90	36.8-143.2	1.028	-1.39	0.998
ISE Potassium	mmol/L	79	2.0-7.3	1.013	-0.04	0.999
ISE Sodium	mmol/L	90	62.4-157.4	1.011	1.39	0.999

Method Comparison Studies (Continued)

In method comparison studies evaluating urine samples, the ILab 600 and the ILab 900 (predicate device) were shown to be statistically similar for the tests listed below.

IL Test	Units	n	Range	Slope	Intercept	r
Amylase	U/L	65	26-6068	0.953	-21	0.999
Calcium	mg/dL	70	20-92	0.923	-0.07	0.995
Creatinine	mg/dL	59	49-263	1.065	4.2	0.992
Glucose Hexokinase	mg/dL	95	4-690	1.027	2.55	0.996
Glucose Oxidase	mg/dL	80	0-801	0.949	4.29	0.997
Phosphorus	mg/dL	60	36-161	0.953	-2.3	0.980
Urea Nitrogen	mg/dL	58	200-1649	1.060	13.7	0.992
Uric Acid	mg/dL	70	9-91	0.989	1.84	0.997
ISE Chloride	mmol/L	50	73-249	1.042	-5.74	0.998
ISE Potassium	mmol/L	49	19-85	1.083	-1.3	0.999
ISE Sodium	mmol/L	49	73-194	1.000	5.36	0.999

In a method comparison study evaluating cerebrospinal fluid samples, the ILab 600 and the ILab 900 (predicate device) were shown to be statistically similar for the test shown below.

IL Test	Units	n	Range	Slope	Intercept	r
Glucose Oxidase	mg/dL	20	40 - 226	0.932	-0.117	1.000

Precision Studies

Two levels of serum samples (except IL Test Cholesterol which used three) were tested in triplicate twice a day for 10 days (20 runs total, n=60) on an ILab 600 Clinical Chemistry System. The results are given below.

IL Test	Serum Sample	Mean	Within Run %CV	Among Run %CV	Among Day %CV	Total %CV
Acid Phos., NP	Level 1	1.51 U/L	8.51	3.24	7.01	11.49
	Level 2	1.75 U/L	9.61	0.00	6.64	11.68
Acid Phos., Total	Level 1	1.9 U/L	5.78	0.00	7.89	9.78
	Level 2	2.5 U/L	4.85	0.00	6.22	7.89
Albumin	Level 1	2.4 g/dL	1.69	0.38	0.44	1.79
	Level 2	4.1 g/dL	1.00	0.41	0.00	1.08
Alk. Phosphatase	Level 1	43 U/L	3.73	3.43	3.94	6.42
	Level 2	187 U/L	1.28	2.78	1.46	3.40
ALT/GPT	Level 1	53 U/L	0.91	0.87	0.00	1.26
	Level 2	101 U/L	0.64	0.37	0.66	0.99
Amylase	Level 1	45 U/L	1.51	0.71	0.00	1.67
	Level 2	149 U/L	0.97	0.23	0.42	1.08
AST/GOT	Level 1	25 U/L	2.28	3.00	0.72	3.83
	Level 2	52 U/L	0.97	0.74	0.00	1.22
Bilirubin, Direct	Level 1	0.18 mg/dL	2.72	5.51	6.98	9.30
	Level 2	2.12 mg/dL	0.86	2.31	3.51	4.29
Bilirubin, Total	Level 1	0.54 mg/dL	2.62	4.70	3.94	6.72
	Level 2	3.70 mg/dL	0.45	0.81	1.13	1.46
Calcium	Level 1	9.0 mg/dL	1.27	0.00	0.66	1.43
	Level 2	13.6 mg/dL	1.00	0.00	0.72	1.23
Cholesterol	Level 1	94 mg/dL	1.66	1.30	0.00	2.11
	Level 2	175 mg/dL	1.31	0.00	0.36	1.35
	Level 3	207 mg/dL	0.92	0.68	0.76	1.37
Cholinesterase	Level 1	2399 U/L	0.52	1.17	6.00	6.13
	Level 2	7078 U/L	0.76	1.42	6.06	6.27
CK/CPK	Level 1	109 U/L	1.95	1.70	2.07	3.31
	Level 2	368 U/L	1.98	2.94	4.28	5.56
CK-MB	Level 1	25.2 U/L	2.74	7.38	4.44	9.04
	Level 2	99.2 U/L	1.08	3.61	2.57	4.56
Creatinine	Level 1	1.0 mg/dL	4.53	0.00	1.51	4.70
	Level 2	4.3 mg/dL	1.29	0.25	0.81	1.54
Glu. Hexokinase	Level 1	83 mg/dL	0.87	0.20	0.28	0.93
	Level 2	263 mg/dL	0.72	0.37	0.00	0.81
Glucose Oxidase	Level 1	73 mg/dL	1.31	0.00	0.75	1.51
	Level 2	248 mg/dL	0.75	0.44	0.34	0.94
γ-GT	Level 1	19 U/L	1.53	1.05	0.97	2.09
	Level 2	123 U/L	0.93	0.41	0.24	1.05
Iron	Level 1	129 µg/dL	0.71	0.00	0.57	0.91
	Level 2	193 µg/dL	0.75	0.40	0.85	1.20
LD-L/LDH-L	Level 1	141 U/L	1.67	0.86	1.69	2.53
	Level 2	442 U/L	1.79	0.66	1.25	2.28

Precision Studies (Continued)

IL Test	Serum Sample	Mean	Within Run %CV	Among Run %CV	Among Day %CV	Total %CV
Lipase	Level 1	19 U/L	9.48	0.00	5.06	10.74
	Level 2	352 U/L	0.84	0.00	2.18	2.34
Magnesium	Level 1	1.86 mg/dL	1.15	3.40	0.00	3.58
	Level 2	5.06 mg/dL	0.90	2.23	2.04	3.16
Phosphorus	Level 1	3.45 mg/dL	1.45	0.00	0.61	1.57
	Level 2	6.44 mg/dL	0.98	0.53	0.00	1.12
TCO2	Level 1	14.92 mmol/L	3.12	0.00	3.30	4.54
	Level 2	30.80 mmol/L	1.26	0.87	2.10	2.60
Total Protein	Level 1	3.8 g/dL	1.13	0.00	0.44	1.21
	Level 2	6.9 g/dL	0.98	0.00	0.38	1.05
Triglycerides	Level 1	64 mg/dL	1.48	2.61	3.18	4.37
	Level 2	197 mg/dL	0.77	0.91	1.66	2.04
Urea Nitrogen	Level 1	15.7 mg/dL	1.05	2.15	5.30	5.82
	Level 2	53.6 mg/dL	0.79	1.59	4.26	4.62
Uric Acid	Level 1	3.3 mg/dL	1.17	3.37	0.48	3.60
	Level 2	7.9 mg/dL	0.77	1.53	0.57	1.80
ISE Chloride	Level 1	83.00 mmol/L	0.69	1.26	0.24	1.45
	Level 2	108.67 mmol/L	0.46	0.58	0.00	0.74
ISE Potassium	Level 1	4.18 mmol/L	1.16	0.00	0.52	1.27
	Level 2	7.20 mmol/L	0.41	0.69	0.77	1.11
ISE Sodium	Level 1	130 mmol/L	0.70	0.38	0.50	0.94
	Level 2	150 mmol/L	0.53	0.20	0.36	0.67

Two levels of urine samples were tested in triplicate twice a day for 10 days (20 runs total, n=60) on an ILab 600 Clinical Chemistry System. The results are given below.

IL Test	Urine Sample	Mean	Within Run %CV	Among Run %CV	Among Day %CV	Total %CV
Amylase	Level 1	139.0 U/L	1.89	1.20	1.26	2.56
	Level 2	410.0 U/L	1.49	1.00	1.10	2.02
Calcium	Level 1	3.9 mg/dL	2.58	0.00	2.19	3.18
	Level 2	5.9 mg/dL	1.67	1.32	1.50	2.50
Creatinine	Level 1	71.6 mg/dL	1.40	0.00	1.58	2.11
	Level 2	108.0 mg/dL	1.11	0.00	1.33	1.73
Glu. Hexokinase	Level 1	63.0 mg/dL	1.78	1.82	2.28	3.41
	Level 2	223.0 mg/dL	1.88	0.00	1.28	2.28
Glucose Oxidase	Level 1	56.0 mg/dL	1.38	1.18	1.85	2.60
	Level 2	201.0 mg/dL	1.32	1.14	0.76	1.91
Phosphorus	Level 1	41.5 mg/dL	2.20	0.92	0.00	2.38
	Level 2	59.0 mg/dL	1.77	0.00	1.41	2.26
Urea Nitrogen	Level 1	493.0 mg/dL	1.49	0.00	0.78	1.68
	Level 2	964.0 mg/dL	1.17	0.43	0.87	1.52
Uric Acid	Level 1	16.2 mg/dL	2.75	0.00	5.69	6.32
	Level 2	28.5 mg/dL	1.92	0.00	2.36	3.05

Precision Studies (Continued)

IL Test	Urine Sample	Mean	Within Run %CV	Among Run %CV	Among Day %CV	Total %CV
ISE Chloride	Level 1	105.0 mmol/L	0.35	0.84	0.19	0.93
	Level 2	203.0 mmol/L	0.44	0.55	0.75	1.03
ISE Potassium	Level 1	25.8 mmol/L	0.26	0.54	1.69	1.79
	Level 2	70.0 mmol/L	0.44	1.02	2.42	2.66
ISE Sodium	Level 1	95.0 mmol/L	0.38	0.43	0.97	1.13
	Level 2	166.0 mmol/L	0.37	0.20	0.50	0.65

Two levels of cerebrospinal fluid samples were tested in triplicate twice a day for 5 days (10 runs total, n=30) using IL Test Glucose Oxidase on an ILab 600 Clinical Chemistry System. The results are given below.

IL Test	CSF Sample	Mean	Within Run %CV	Among Run %CV	Among Day %CV	Total %CV
Glucose Oxidase	Level 1	45.5 mg/dL	1.50	0.47	0.00	1.49
	Level 2	90.3 mg/dL	0.77	0.46	0.45	0.98



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 21 1998

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Re: K980757
ILab™ 600 Clinical Chemistry System
Regulatory Class: II
Product Code: CGZ, CEK, CEM, CFJ, CFR, CGA, CGS, CGX,
CIC, CIG, CIT, CIX, CJE, CKB, DIH, JFJ, JGJ, JGS, JIX,
JJW, JJX, JJY, KHS
Dated: February 26, 1998
Received: February 27, 1998

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 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.

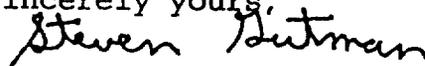
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
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Enclosure

