

AUG 19 1997

## SECTION 3

**IL Test™ ContrIL Spectrum - 510(k) SUMMARY**  
**(Summary of Safety and Effectiveness)**

**Submitted by:**

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 Director, Regulatory Affairs  
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**Contact persons:**

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**Summary prepared:**

July 28, 1997

**Name of the device:**

IL Test™ ContrIL Spectrum

**Classification name(s):**

862.1660	Quality Control Material (Assayed and Unassayed)	Class I
75JJS	Controls for Blood-Gases (Assayed and Unassayed)	
75JJR	Electrolyte Controls (Assayed and Unassayed)	

**Identification of predicate devices:**

K963800	IL Test™ ContrIL PLUS for monitoring pH/pCO <sub>2</sub> /pO <sub>2</sub> /Na <sup>+</sup> /K <sup>+</sup> /Ca <sup>++</sup> /Cl <sup>-</sup> /Glucose
K945677	IL Test™ Multi-4 (Levels 1, 2 and 4) for monitoring THb/O <sub>2</sub> Hb/COHb/MetHb/RHb

**Description of the device/intended use(s):**

IL Test™ ContrIL Spectrum is an *in vitro* diagnostic quality control material equilibrated with specific concentrations of carbon dioxide and oxygen and with a known level of sodium, potassium, calcium, chloride and glucose and available in three levels to simulate clinically significant conditions of acid base, electrolytes and glucose balance and oxygenation status. The following parameters can be monitored with IL Test™ ContrIL Spectrum: pH/pCO<sub>2</sub>/pO<sub>2</sub>/Na<sup>+</sup>/K<sup>+</sup>/Ca<sup>++</sup>/Cl<sup>-</sup>/Glucose/THb/O<sub>2</sub>Hb/COHb/MetHb/RHb.

**Statement of how the technological characteristics of the device compared to the predicate device:**

IL Test™ Spectrum is substantially equivalent in performance, intended use, safety and effectiveness to the predicate devices: IL Test™ ContrIL PLUS for monitoring pH/pCO<sub>2</sub>/pO<sub>2</sub>/Na<sup>+</sup>/K<sup>+</sup>/Ca<sup>++</sup>/Cl<sup>-</sup>/Glucose and IL Test™ Multi-4 Control for monitoring THb/O<sub>2</sub>Hb/COHb/MetHb/RHb.

**SECTION 3 (Continued)**  
**IL Test™ ContrIL Spectrum - 510(k) SUMMARY**  
**(Summary of Safety and Effectiveness)**

Summary of performance data:

Parameter	Level 1		Level 2		Level 3	
	Grand Mean	Within Run %CV	Grand Mean	Within Run %CV	Grand Mean	Within Run %CV
pH	7.59	0.03	7.41	0.02	7.13	0.03
pCO <sub>2</sub> (mmHg)	20.80	1.98	37.81	1.81	64.91	1.43
pO <sub>2</sub> (mmHg)	145.94	1.69	87.80	3.71	52.05	4.89
Na <sup>+</sup> (mm/L)	114.66	0.62	137.46	0.40	157.20	0.59
K <sup>+</sup> (mm/L)	2.57	2.93	4.33	1.65	5.99	1.04
Ca <sup>++</sup> (mm/L)	0.62	1.82	1.00	1.40	1.54	1.69
Cl <sup>-</sup> (mm/L)	83.06	0.66	110.03	0.53	137.60	0.40
Glu (mg/dL)	60.74	3.79	84.49	2.43	233.29	2.04
THb	7.1	3.64	13.4	3.35	18.0	2.73
%COHb	54.1	0.32	4.0	1.17	96.6	0.06
%O <sub>2</sub> Hb	44.9	0.38	93.6	0.13	1.9	0
%MetHb	0.5	3.21	1.8	5.77	1.5	5.30
%RHb	0.5	1.85	0.6	3.86	0.002	4.40



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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Betty Lane  
Director  
Regulatory Affairs  
Instrumentation Laboratory Company  
113 Hartwell Avenue  
Lexington, MA 02173

Re: K972861  
IL Test ContrIL Spectrum  
Regulatory Class: I  
Product Code: JJS  
Dated: August 1, 1997  
Received: August 4, 1997

Dear Ms. Lane:

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 (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 requirement, 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.

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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 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: IL Test™ ContrIL Spectrum

### Indications for Use:

IL Test™ ContrIL Spectrum is an *in vitro* diagnostic quality control material equilibrated with specific concentrations of carbon dioxide and oxygen and with a known level of sodium, potassium, calcium, chloride and glucose and available in three levels to simulate clinically significant conditions of acid base, electrolytes and glucose balance and oxygenation status. The following parameters can be monitored with IL Test™ ContrIL Spectrum: pH/pCO<sub>2</sub>/pO<sub>2</sub>/Na<sup>+</sup>/K<sup>+</sup>/Ca<sup>++</sup>/Cl<sup>-</sup>/Glucose/THb/O<sub>2</sub>Hb/COHb/MetHb/RHb.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Therese J. Calvia for A. Montgomery*  
(Division Chief-ODE)

Division of Clinical Laboratory Devices

510(k) Number K973861

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.019)

OR

Over-The-Counter Use \_\_\_\_\_