DEC 1 9 2003

AKERS
BIOSCIENCES INC.

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is **K031579**.

807.92 (a)(1):

Name: Akers Laboratories, Inc.
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Contact: Barbara A. Bagby

807.92 (a)(2): Device Name – trade name and common name, and classification

Trade name: InstaRead™ Lithium System

Common name: Lithium test system

Classification: 21 CFR 862.3560
Product Code: JIH

807.92 (a)(3): Identification of the legally marketed predicate device

InstaRead™ Lithium System is substantially equivalent to the Vitros Lithium System, Johnson & Johnson Clinical Diagnostics, Inc.- Rochester, NY K934106.

807.92 (a)(4): Device Description

The InstaRead™ Lithium System is an *in vitro* diagnostic device designed to provide accurate and precise measures of patient lithium blood levels using serum or whole blood specimens in an easy to use system that can be utilized at the point of care by non-clinical laboratory personnel

The system consists of three key components starting with the Blood Cell Separator which is intended for use as a sample preparation aid to *in vitro* diagnostic testing systems where precise, micro-volume samples of a cell depleted fraction is required to be collected from a whole blood specimen. This is achieved through the attraction and capture of blood cells from a whole blood

specimen by the lectin coating on the membrane. The residual liquid fraction, cell depleted continues to flow laterally to the tip of the membrane at which time the capillary pipette that has been inserted into the designated hole in the separator fills to the pipette's fixed volume and is ready to use.

The precise volume (0.2 ì l) that is captured using the separator is introduced to the second key component of the system, the Lithium Reagent. The lithium reagent is a colorimetric reagent whose active ingredient is a porphyrin compound that is highly specific and sensitive to lithium. Absorbance of light at 505 nm is increased by lithium concentration and is linear from 0.1 to 3.0 mEq/L of lithium, although the reportable range has been limited to 2.5 mEq/L.

The third key component of the system is the InstaRead™ Lithium System photometric reader which is designed to measure the absorbance at 505 nm of a solution contained in a cuvette and report concentrations from 0.0 to 2.5 mEq/L of lithium on the reader's display system.

807.92 (a)(5): Intended use

The InstaRead™ Lithium System is intended to measure lithium blood levels. Measurements of lithium are used to aid in the management of individuals taking lithium for the treatment of mental disturbances, such as manic-depressive illness (bipolar disorder). The test is targeted for physician's office use, and may be used with whole blood, serum, or EDTA-plasma.

807.92 (a)(6): Technological Similarities and Differences to Predicate

The following chart exhibits similarities and differences between the InstaRead™ Lithium System and the Vitros Lithium System.

CHARACTERISTIC	InstaRead™ Lithium System	Vitros Lithium System K934106
Intended Use	Measures lithium levels in Serum, plasma and whole blood	Measures lithium levels in serum and plasma
Indications for Use	Used in the management and monitoring of lithium levels in psychiatric patients treated with lithium for manic depression illness	Used in the management and monitoring of lithium levels in psychiatric patients treated with lithium for manic depression illness
Detection Methodology	Colorimetric Spectrophotometry	Colorimetric Spectrophotometry
Test Sample	Serum; finger stick and venous EDTA whole blood and EDTA plasma	Serum; sodium heparin and EDTA plasma
Reading System	Handheld; battery powered reader	Benchtop; AC Analyzer
Testing Environment	Point of Care	Laboratory Use
Reactive Ingredient	Lithium Sensitive Dye	Lithium Sensitive Dye
Preparation Materials	Provided	Not Provided
Calibration Requirements	Start of each refill pack (24 tests); system service or maintenance, out of range quality control results; or once every month	Lot number changes; system service or maintenance, out of range quality control results; or once every six months
Performance Range	0.1 mEq/L to 2.5 mEq/L	0.2 mEq/L to 4.0 mEq/L
Sensitivity	0.1 mEq/L	0.2 mEq/L
Correlation Coefficient to Predicate System	0.962	0.991
Analyte Limitations: Sodium Potassium Calcium Magnesium Iron Zinc Copper Hemoglobin Free Bilirubin	 200 mmol/L 8.0 mmol/L 4.0 mmol/L 2.0 mol/L 200 umol/L 250 umol/L 250 umol/L 1000 mg/dL 45 mg/dL	 160 mmol/L 10.0 mmol/L 5.0 mmol/L 5.0 mol/L 124 umol/L 770 umol/L 470 umol/L 100 mg/dL 20 mg/dL

The differences in the two testing platforms do not raise new issues of safety and effectiveness.

807.92 (b)(1): Brief Description of Non-clinical Data

Studies were performed to evaluate the sensitivity, linearity, and precision of the InstaRead™ Lithium System. These studies demonstrated that the assay was sensitive to 0.1 mEq/L, the assay was linear between 0.1 and 2.5 mEq/L, and that precision estimates ranged from 0.00 to 0.08 standard devations (SDs) when samples, targeted at various levels throughout the range, were assayed in multiple runs over multiple days. The percent coefficient of variation (%CV) of a control at ~1.5 mEq/L lithium was 6.4% when tested in 50 runs over five days (10 runs per day).

807.92 (b)(2): Brief Description of Clinical Data

The InstaRead™ Lithium System was compared to a conventional laboratory system at two different clinical sites with a total of 200 serum samples (100 samples per site). The data showed the following linear regression and summary statistics:

SERUM STUDY LINEAR REGRESSION

		SLOPE		Y-INTERCEPT			
SITE	n	slope	95% CI*	y-intercept	95% CI*	$S_{y/x}$	"r"
1	100	0.970	0.918 to 1.022	0.03	-0.04 to 0.10	0.14	0.966
2	100	1.025	0.966 to 1.085	-0.07	-0.15 to 0.02	0.17	0.961
Total	200	0.998	0.958 to 1.038	-0.02	-0.07 to 0.04	0.16	0.962

*CI = Confidence Intervals

In a second study, 29 spiked whole blood samples were assayed by the InstaRead™ Lithium System at a doctor's office, and the corresponding plasma samples were assayed by a routine chemistry analyzer. The data appear below.

WHOLE BLOOD STUDY LINEAR REGRESSION

	SLOPE		Y-INTERCEPT			
n	slope	95% CI	y-int	95% CI	$S_{y/x}$	"r"
29	0.833	0.772 to 0.895	0.05	-0.03 to 0.13	0.10	0.983

Two separate studies were conducted to evaluate InstaRead performance with fingerstick whole blood samples. One study included 40 native fingerstick samples, and the second study included 20 samples. In each study, two fingerstick samples were assayed by the InstaRead™ Lithium System at a doctor's office, and venous blood was collected into a neutral tube and processed to serum. The serum was assayed by atomic absorption at a reference laboratory. The two data appear below

FINGERSTICK STUDY #1 LINEAR REGRESSION

	SLOPE		Y-INTERCEPT			
n	slope	95% CI	y-int	95% CI	$S_{y/x}$	"r"
40	0.847	0.735 to 0.958	0.02	-0.07 to 0.11	0.14	0.928

FINGERSTICK STUDY #2 LINEAR REGRESSION

	SLOPE		Y-INTERCEPT			
n	slope	95% CI	y-int	95% CI	$S_{y/x}$	"r"
20	1.194	1.129 to 1.258	0	-0.06 to 0.06	0.06	0.994

807.92 (b)(3): Conclusions from Non-clinical and Clinical Testing

InstaRead™ Lithium System was evaluated for non-clinical and clinical performance characteristics in comprehensive studies. These studies demonstrated that the test is safe and effective for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 9 2003

Ms. Erika B. Ammirati
Regulatory Consultant
Akers Biosciences Inc.
201 Grove Road
Thorofare, NJ 08086

Re: k031579
Trade/Device Name: InstaRead™ Lithium System
Regulation Number: 21 CFR 862.3560
Regulation Name: Lithium test system
Regulatory Class: Class II
Product Code: JIH
Dated: September 24, 2003
Received: September 24 24, 2003

Dear Ms. Ammirati:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K031579

Device Name: InstaRead™ Lithium System

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031579