510(k) SUMMARY

A. Name of Device and Classification

Trade Name: Bartels Legionella Urinary Antigen ELISA Test

Classification: Bartels Legionella Urinary Antigen ELISA Test is an enzyme-linked immunoassay that detects *Legionella pneumophila* Serogroup 1 antigen in human urine. This test has been classified as a Class II (performance standards) device, product code MJH (21 CFR 866.3300).

B. Legally Marketed Device

Bartels Legionella Urinary Antigen ELISA Test claims substantial equivalence to the Binax Legionella Urinary Antigen EIA.

C. Device Description

Bartels Legionella Urinary Antigen ELISA Test is an enzyme-linked immunoassay intended for the qualitative detection of *Legionella pneumophila* Serogroup 1 antigen in human urine. The kit consists of microelisa stripwells with lid, positive and negative control reagents, conjugate, wash concentrate, colorimetric substrate (2 components) and stop solution. Sufficient materials are provided to perform 96 analyses.

The microelisa wells have been pre-coated with purified rabbit antibodies to *Legionella pneumophila* Serotype 1 (capture antibody). An undiluted urine specimen (100 µL), or positive or negative controls (100 µL each) are each placed in a single microelisa well followed by the addition of 50 µL of Conjugate (horseradish peroxidase-conjugated rabbit antibodies to *L. pneumophila*). The loaded microelisa plate is then covered with the lid and incubated for 48 to 52 minutes at 34-37°C followed by 4 cycles of wash/aspiration using diluted Wash Solution (manual or automated wash procedure). Colorimetric substrate (tetramethyl benzidine/H_2O_2 100 µL/well) is then added and incubated for 10 to 12 minutes at 34-37°C followed by the addition of Stop Solution (1M Phosphoric acid, 100 µL/well). The stopped plate is then read on a microelisa plate reader at 450 nm against an air blank. For a test to be considered valid, the Negative Control must have an optical density (OD) value of less than 0.100 and the Positive Control must be greater than the Positive Cutoff (pco). The pco is equal to 4X the O.D. value of the Negative Control value. Any specimen with an O.D. value ≥ the pco is considered positive. Any specimen with an O.D. value < the pco is considered negative. Alternatively, the results can be visually read. For this purpose, a visual interpretation card, and written instructions, are provided in the kit for interpretation of results. Any well that produces definite yellow color is considered to be positive.

The following components are provided in each Bartels LUA ELISA kit:

1. Micro Wells, 96 break-away coated wells with purified rabbit anti-*Legionella pneumophila* Serogroup 1, IgG fraction. Ready to use. Store at 2-8°C.
2. Conjugate, 6.5 mL bottle of purified rabbit anti-*Legionella pneumophila* Serogroup 1 IgG conjugated to horseradish peroxidase (HRP) in a buffer with protein stabilizer in a red tracking dye. Ready to use. Store at 2-8°C.
3. Wash Concentrate (20X), 100 mL bottle of buffered saline with detergent and thimerosal. 20X concentrate; dilute 1:20 with distilled or deionized water before use. Store at 2-30°C.
4. Substrate A, 12mL bottle of tetramethyl benzidine (TMB). Ready to use. Store at 2-8°C.
5. Substrate B, 12mL bottle of hydrogen peroxide (H_2O_2). Ready to use. Store at 2-8°C.
6. Stop Solution, 12mL bottle of 1M phosphoric acid. Ready to use. Store at 2-30°C.
7. Positive Control, 1.5mL bottle of human urine containing *Legionella pneumophila* serogroup 1 antigen and preservative. Ready to use. Store at 2-8°C.
8. Negative Control, 1.5mL bottle of normal human urine and preservative. Ready to use. Store at 2-8°C.
9. Visual Interpretation Card – Visual interpretation card displaying 5 levels of yellow color intensity.
10. Package Insert, Detailed description of test procedure and interpretation of results.

D. Intended Use

Bartels Legionella Urinary Antigen ELISA Test is intended as an adjunct to culture for the presumptive diagnosis of past or current Legionnaires' Disease by qualitative detection of *Legionella pneumophila* Serogroup 1 antigen in human urine.

E. Comparison with the Predicate Device

Bartels Legionella Urinary Antigen ELISA Test, by the antigen capture sandwich ELISA technique described in this application, is substantially equivalent to the currently marketed Binax Legionella Urinary Antigen EIA which has been cleared by FDA through 510(k) premarket notification. Both kits share common intended use statements, target populations, design/format, kit materials, performance characteristics, absence of risk to patients, specimen type and analytes. The following table (Table 1) summarizes the similarities

Table 1: Comparison of Devices		
Product Name	**Bartels Legionella Urinary Antigen ELISA Test**	**Binax Legionella Urinary Antigen EIA**
Intended Use Statement	"Bartels Legionella Urinary Antigen ELISA Test is intended as an adjunct to culture for the presumptive diagnosis of past or current Legionnaires' Disease by qualitative detection of *Legionella pneumophila* Serogroup 1 antigen in human urine."	"This kit is an enzyme immunoassay (EIA) based system intended for in vitro diagnostic use to qualitatively detect the presence of *Legionella pneumophila* Serogroup 1 antigen (L. pneumophila Serogroup 1 antigen) in human urine as an adjunct to culture for the presumptive diagnosis of past or current Legionnaires' Disease."
Target Population	Individuals suspected of acute infection by *Legionella pneumophila* Serotype 1.	Individuals suspected of acute infection by Legionella *pneumophila* Serotype 1.
Design/format	Antigen capture (sandwich) enzyme immunoassay.	Antigen capture (sandwich) enzyme immunoassay.
Materials	Microelisa stripwells coated with rabbit polyclonal antibodies to *L. pneumophila* Serotype 1, HRP polyclonal antibodies to *L. pneumophila* Serotype 1, positive and negative controls, wash concentrate, tetramethyl benzidine/H_2O_2 (TMB) colorimetric substrate, stop solution, visual interpretation card, package insert.	Microelisa stripwells coated with rabbit polyclonal antibodies to *L. pneumophila* Serotype 1, HRP polyclonal antibodies to *L. pneumophila* Serotype 1, positive and negative controls, wash concentrate, tetramethyl benzidine/H_2O_2 (TMB) colorimetric substrate, stop solution, package insert.
Performance Characteristics (Described in Section 10).	Using culture method as "gold standard": Sensitivity: 94.7% Specificity: 91.1% Accuracy: 92.3%	Using culture method as "gold standard": Sensitivity: 87.2% Specificity: 86.7% Accuracy: 86.9%
Risk to patient	No unique issues of safety or effectiveness.	No unique issues of safety or effectiveness.
Specimen Type	Voided urine.	Voided urine.
Analyte	*Legionella pneumophila* Serotype 1 soluble urinary antigen.	*Legionella pneumophila* Serotype 1 soluble urinary antigen.

of Bartels Legionella Urinary Antigen ELISA Test and Binax Legionella Urinary Antigen EIA:

F. Performance Data

A clinical study was performed on 274 clinically well-defined urine specimens at a major infectious disease reference laboratory. The study consisted of: a) 94 urine specimens from patients whose respiratory specimens were culture-positive for *Legionella pneumophila* Serogroup 1; b) 150 urine specimens from who did not have a diagnosis of *Legionella pneumophila*; and c) 30 urine specimens from normal healthy volunteers. The Bartels Legionella Urinary Antigen ELISA Test had a sensitivity of 94.7%, specificity of 91.1% and accuracy of 92.3%. Substantial equivalence was established between the Bartels LUA and the predicate device.

In this study, a comparison was also made for the Bartels LUA ELISA Test between results obtained with the automated plate reader vs. the use of a visual interpretation card. The sensitivity of the visual interpretation was 92.6%, specificity was 93.9% and accuracy was 93.4%.

G. Conclusion

The Bartels Legionella Urinary Antigen ELISA Test is substantially equivalent to the Binax Legionella Urinary Antigen EIA. Furthermore, with the Bartels LUA ELISA Test, there is equivalence between reading the results with an automated plate reader and performing a visual interpretation.

Name of Submitter:

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Name of Contact Person:

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Date Prepared: March 30, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

Ms. Sheryl Ruppel
Regulatory Affairs Manager
INTRACEL Corporation
1330 Piccard Drive
Rockville, Maryland 20850

Re: K991074
Trade Name: Bartels Legionella Urinary Antigen ELISA Test
Regulatory Class: II
Product Code: MJH
Dated: November 19, 1999
Received: November 19, 1999

Dear Ms. Ruppel:

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 at (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

510(k) Number (if known): K991074

Device Name: Bartels Legionella Urinary Antigen ELISA Test

Indications For Use:

Bartels Legionella Urinary Antigen ELISA Test is intended as an adjunct to culture for the presumptive diagnosis of past or current Legionnaires' Disease by qualitative detection of Legionella pneumophila serogroup 1 antigen in human urine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991074

Prescription Use X OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)