

AUG 21 1998

K982238



Binax, Inc.
Binax NOW™ Legionella Urinary Antigen Test
510(k) Notification

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Binax NOW™ Legionella Urinary Antigen Test

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

Submitter: Binax, Inc.
217 Read Street
Portland, Maine 04103

Attention: Pamela S. Angell
(207) 772-3988 Office
(207) 871-5751 FAX

Trade Name: Binax NOW™ Legionella Urinary Antigen Test

Common Name: Legionella ICT

Classification Name: Haemophilus spp. serological reagents (per 21 CFR 8660.3300)

Predicate Device: Binax Legionella Urinary Antigen EIA, 510(k) number K934965/S1

Device Description: The Binax NOW™ Legionella Urinary Antigen Test is an immunochromatographic membrane assay to detect Legionella pneumophila serogroup 1 antigen in human urine. A test strip, containing gold-conjugated and immobilized anti-Legionella pneumophila serogroup 1 antibodies, and a swab well are mounted on opposite sides of a cardboard, book-shaped hinged test device. A dacron swab is dipped into the urine to be tested and then inserted into the swab well. A single reagent is added to the swab well from a dropper bottle before closing the test device. Soluble antigen captured by immobilized anti-Legionella pneumophila serogroup 1 antibody reacts to bind the visualizing gold-conjugate. There are no transferring steps, the sample is contained, and results are available within 15 minutes.

Binax, Inc.
217 Read Street
Portland, Maine 04103 USA

Administrative Offices
Phone:207-772-3988

Customer Service
Phone:800-323-3199

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Continued)**

Intended Use: The Binax NOW™ Legionella Urinary Antigen Test is intended for *in vitro* diagnostic use to qualitatively detect the presence of *Legionella pneumophila* serogroup 1 soluble antigen in human urine. The indication statements are the same as those made for the predicate device.

Technological Characteristics: Both the Binax NOW™ Legionella Urinary Antigen and the Binax Legionella Urinary Antigen EIA tests use a solid phase coated with polyclonal rabbit antibody to detect *Legionella pneumophila* serogroup 1 antigen in human urine samples. However, the predicate device is an enzyme immunoassay (EIA) employing a horseradish peroxidase conjugate and a microtiter well solid phase, while the Binax NOW™ Legionella Urinary Antigen Test is an immunochromatographic assay utilizing a colloidal gold conjugate and a membrane solid phase. Furthermore, the predicate device is a multi-step assay requiring calculation of a ratio for result interpretation while the NOW™ membrane test is a simple and rapid test interpreted visually by the presence or absence of two pink-to-purple colored lines.

Performance Summary: The Binax NOW™ Legionella Urinary Antigen Test for *Legionella pneumophila* serogroup 1 antigen in urine is substantially equivalent to the predicate device, Binax Legionella Urinary Antigen EIA (K934965/S1). The performance of the Binax NOW™ Legionella Urinary Antigen Test was verified by sensitivity, specificity, and reproducibility studies using well characterized frozen urine specimens and volunteer urine donors. Refer to attached **PERFORMANCE CHARACTERISTICS**.

Signed J. Georges Nitis
J. Georges Nitis, Ph.D., MBA
Director, Regulatory Affairs

Date 2/16/98

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Continued)**

PERFORMANCE CHARACTERISTICS

BINAX NOW™ LEGIONELLA URINARY ANTIGEN TEST

Sensitivity and Specificity:

Because of the low rate of positivity of *Legionella pneumonia*, test sensitivity and specificity were determined by testing 300 well characterized frozen urine specimens in both the Binax NOW™ Legionella (NOW™) and in the Binax Legionella Urinary Antigen EIA (EIA) Tests. The University of Indiana conducted all testing. EIA and NOW™ test sensitivity and specificity were calculated based on performance versus Clinical Diagnosis. Specimens were considered true positives when the presence of infection was confirmed by culture, RIA, DFA or IFA.

NOW™ test sensitivity is 97% compared to 95% for the predicate device. NOW™ test specificity is 98% compared to 94% for the predicate device.

Cross-Reactivity:

The 200 urines presumed negative for *Legionella pneumophila* serogroup 1 were positive for other bacterial or fungal pneumonia or urinary tract infections, allowing a comparison of the NOW™ and predicate device cross-reactivities. One hundred ninety six (196) of the 200 patient specimens produced negative results in the NOW™ test for a specificity of 98%.

To further demonstrate Binax test specificity, 106 presumed negative urine specimens were tested in the Binax NOW™ Legionella Urinary Antigen Test. All specimens tested negative.

Reproducibility:

A blind study of the NOW™ test was conducted at 3 separate sites using a panel of coded specimens containing negative, low positive, moderate positive and high positive swabs. Individuals of diverse educational backgrounds performed testing on 3 different days. One hundred percent (100%) of the 360 samples tested were correctly interpreted.

Quality Control:

The ability of the Binax NOW™ Legionella Urinary Antigen Test control to indicate test failure was evaluated when 3 operators each ran 20 kit controls in a panel of 20 devices, 9 of which had been rendered inoperative. The number of defective devices and the defect itself were not apparent to the operator. All 60 devices were correctly interpreted as positive, negative, or invalid.

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**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Continued)**

**PERFORMANCE CHARACTERISTICS
BINAX NOW™ LEGIONELLA URINARY ANTIGEN TEST**

Preliminary Stability:

Preliminary stability studies of the Binax NOW™ Legionella Urinary Antigen Test are ongoing.



AUG 21 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Pamela S. Angell
Program Manager
Binax, Inc.
217 Read Street
Portland, Maine 04103

Re: K982238
Trade Name: Binax NOW™ *Legionella* Urinary Antigen Test
Regulatory Class: II
Product Code: MJH
Dated: August 12, 1998
Received: August 13, 1998

Dear Ms. Angell:

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.

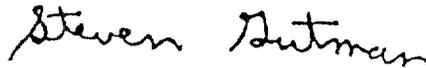
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (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
Center for Devices and Radiological Health

Enclosure

Binax, Inc.
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APPENDIX B

INDICATIONS FOR USE FORM

510(k) Number (if known): K982238

Device Name: Binax NOW™ Legionella Urinary Antigen Test

Indications For Use:

The Binax NOW™ Legionella Urinary Antigen Test is a rapid immunochromatographic assay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen (*L. pneumophila* serogroup 1 antigen) in human urine as an adjunct to culture for the presumptive diagnosis of Legionnaires' Disease. It is intended for *in vitro* diagnostic use.

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 K982238

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)