510(k) Summary

K070522

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

SUBMITTER

Binax, Inc.
d/b/a Inverness Medical Professional Diagnostics
10 Southgate Road
Scarborough, Maine 04074

MAR 15 2007

CONTACT PERSON

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ALTERNATE CONTACT

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DATE PREPARED

February 13, 2007

TRADE NAME

Binax NOW® *Legionella* Urinary Antigen Test

COMMON NAME

Legionella ICT

CLASSIFICATION NAME

Haemophilus spp. Serological reagents (per 21 CFR 866.3300)

PREDICATE DEVICE

Binax NOW® *Legionella* Urinary Antigen Test (unmodified) 510 (k) number K982238

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. Legionella urinary antigen captured by immobilized anti-*Legionella pneumophila* antibody reacts to bind anti-*Legionella pneumophila* conjugated antibody, forming the Sample Line. Immobilized control antibody captures anti-species conjugate, forming the Control Line. There are no transferring steps, the sample is contained, and results are available in 15 minutes.

INTENDED USE

The Binax NOW® *Legionella* Urinary Antigen Test is an *in vitro* rapid immunochromatographic assay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen (*L. pneumophila* serogroup 1 antigen) in urine specimens from patients with symptoms of pneumonia. It is intended to aid in the presumptive diagnosis of *Legionella* infection ("Legionnaires" Disease) caused by *L. pneumophila* serogroup 1 in conjunction with culture and other methods.

TECHNOLOGICAL CHARACTERISTICS

The Binax NOW® *Legionella* Urinary Antigen Test uses lateral flow immunochromatographic technology. The test is a rapid immunoassay that employs specific antibodies immobilized onto a solid phase to capture and visualize *Legionella pneumophila* serogroup 1 antigen. (The modified and cleared Binax NOW® *Legionella* Urinary Antigen Tests share the same technological characteristics and antigen detection reagents. Assay procedure, intended use and product claims are unchanged for the modified device.)

PERFORMANCE SUMMARY

Stability, Method Comparison, Cross Reactivity and Loss of Signal testing were performed on the modified device to ensure its equivalence to the unmodified device. The changes to the NOW® *Legionella* Urinary Antigen Test have not affected its safety or effectiveness as detailed below:

STABILITY STUDIES:

Stability studies of the modified test are currently ongoing.

METHOD COMPARISON:

Seventy (70) urine samples, collected from presumed healthy individuals, were tested on the modified and cleared devices yielding negative results and demonstrating 100% agreement between the two devices. Fifteen (15) known positive urine specimens were tested on the modified and unmodified devices yielding positive results and again demonstrating 100% agreement.

CROSS-REACTIVITY TESTING:

In the original 510(K) submission, cross reactivity testing was performed using urines from patients diagnosed with other (non-*Legionella*) bacterial or fungal pneumonia or urinary tract infections. In lieu of this, whole organism cross-reactivity testing was performed to compare the modified and unmodified devices.

Given that modifications to the device do NOT impact the detection portion of the assay, a limited cross-reactant panel of 11 organisms was tested. The panel included organisms associated with pneumonia as well as those likely to be found in the urogenital tract as normal flora or as the result of a urinary tract infection. None of the organisms, grown in culture and tested at clinically relevant concentrations (depending on the organism 1×10^6 to 2×10^9), tested positive on the modified test.

LOSS OF SIGNAL (LOS) TESTING:

Serial two-fold dilutions of a known positive urine specimen were run on the unmodified and modified devices. Three (3) separate lots of the modified device were tested against

unmodified devices. In all three studies, the same dilution of the positive urine provided loss of signal on both the unmodified and modified devices.

Signed Pamela Angell Date 2/16/07
Pamela Angell, Director, Worldwide Clinical Affairs
Binax, Inc. d/b/a Inverness Medical Professional Diagnostics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Karen Mortimer
Clinical Affairs Specialist
Binax, Inc.
Inverness Medical Professional Diagnostics
10 Southgate Road
Scarborough, ME 04074

MAR 15 2007

Re: k070522
Trade/Device Name: BinaxNOW® *Legionella* Urinary Antigen Test
Regulation Number: 21 CFR 866.3300
Regulation Name: Haemophilus spp. serological reagents
Regulatory Class: Class II
Product Code: MJH
Dated: February 14, 2007
Received: February 23, 2007

Dear Ms. Mortimer:

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.

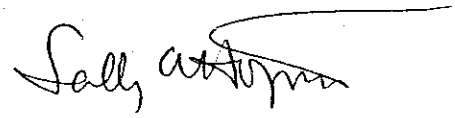
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070522

Device Name: BinaxNOW® *Legionella* Urinary Antigen Test

Indications For Use:

The Binax NOW® *Legionella* Urinary Antigen Test is an in vitro rapid immunochromatographic assay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen (*L. pneumophila* serogroup 1 antigen) in urine specimens from patients with symptoms of pneumonia. It is intended to aid in the presumptive diagnosis of *Legionella* infection (Legionnaires' disease) caused by *L. pneumophila* serogroup 1 in conjunction with culture and other methods.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Freddie Lu-Poole

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K070522