510(k) SUMMARY

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 K091766.

FEB 2 4 2010

SUBMITTER
Binax, Inc.
10 Southgate Road
Scarborough, Maine 04074
(207) 730-5733 (Office)
(207) 730-5717 (FAX)
Establishment Registration Number: 1221359

CONTACT PERSON
Suzanne Vogel
suzanne.vogel@invmed.com (email)

DATE PREPARED
February 10, 2010

TRADE NAME
Clearview® Exact PBP2a Test

COMMON NAME
Clearview® Exact PBP2a Test, Clearview® Exact PBP2a, Clearview® PBP2a

CLASSIFICATION NAME
System, Test, Genotypic Detection, Resistant Markers, *Staphylococcus* Colonies (MYI) (per 21 CFR 866.1640)

PREDICATE DEVICES
Mueller Hinton Agar w/4% NaCl w/Antibiotics (Remel) K850291
PBP2' Latex Agglutination Test (Oxoid) K011710

DEVICE DESCRIPTION
The Clearview® Exact PBP2a Test is a rapid immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect the PBP2a protein directly from bacterial isolates. These antibodies and a control antibody are immobilized onto a nitrocellulose membrane as two distinct lines and combined with a sample pad, a blue conjugate pad, and an absorption pad to form a test strip.

Isolates are sampled directly from the culture plate and eluted into an assay tube containing Reagent 1. Reagent 2 is then added and the dipstick is placed in the assay tube. Results are read visually at 5 minutes.

INTENDED USE

The Clearview® Exact PBP2a Test is a qualitative, *in vitro* immunochromatographic assay for the detection of penicillin-binding protein 2a (PBP2a) in isolates identified as *Staphylococcus aureus*, as an aid in detecting methicillin-resistant *Staphylococcus aureus* (MRSA). The Clearview® Exact PBP2a Test is not intended to diagnose MRSA nor to guide or monitor treatment for MRSA infections.

TECHNOLOGICAL CHARACTERISTICS

The Clearview® Exact PBP2a Test and the Oxoid PBP2' Latex Agglutination Test (K011710) utilize similar technologies to detect PBP2a in MRSA. Both tests use detection with latex conjugates sensitized with a monoclonal antibody against PBP2a.

The Remel Mueller Hinton Agar (K850291) utilizes a different technology involving microbial growth on Mueller Hinton Agar with 4% NaCl and 6 µg/mL Oxacillin.

PERFORMANCE SUMMARY

Clinical Performance

The clinical performance of the Clearview® Exact PBP2a Test was established in a multi-center clinical study conducted in 2009 at three geographically-diverse laboratories.

A total of 457 *S. aureus* samples were evaluated in the Clearview® Exact PBP2a Test, compared to results of 30 µg cefoxitin disk diffusion and interpreted according to CLSI standards. Performance results by plate type are listed in Table 1 below.

Table 1: Clearview® Exact PBP2a Test Performance Compared to Cefoxitin (30 µg) Disk Diffusion in *S. aureus* Isolates: Results by Plate Type

Plate Type	Sensitivity	95% C.I.	Specificity	95% C.I.
Tryptic Soy Agar with 5% sheep blood	98.1% (206/210)	(95.2-99.3%)	98.8% (244/247)	(96.5-99.6%)
Columbia Agar with 5% sheep blood	99.0% (208/210)	(96.6-99.7%)	98.8% (244/247)	(96.5-99.6%)
Mueller Hinton with 1 µg oxacillin induction	99.5% (209/210)	(97.4-99.9%)	98.8% (244/247)	(96.5-99.6%)

Analytical Performance

Analytical Reactivity and Specificity

162 strains of methicillin-resistant *Staphylococcus aureus* (MRSA) and 112 strains of methicillin-sensitive *Staphylococus aureus* (MSSA) were tested in the Clearview® Exact PBP2a Test with expected results. These bacterial strains were obtained from the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA), American Type Culture Collection (ATCC) and a collection of strains from Department of Infectious Disease Epidemiology of the Imperial College in London, England.

Reproducibility Study
A study of the Clearview® Exact PBP2a Test was conducted at 3 separate sites using panels of blind coded specimens containing negative and positive samples. Participants tested each sample twice on 5 different days. There was 97.3% (580/596) agreement with expected test results.

Signed_____ Date _____
Suzanne M. Vogel, MPH
Clinical Affairs
Binax, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

FEB 2 4 2010

Binax, Inc
c/o Suzanne M. Vogel
10 Southgate Road
Scarborough, Maine 04074

Re: K091766
Trade/Device Name: Clearview® Exact PBP2a Test. Model 891-000
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: MYI
Dated: February 19, 2010
Received: February 22, 2010

Dear Ms. Vogel:

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 class II (Special Controls), 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.

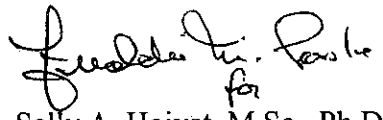
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for

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 Form

510(k) Number (if known): _K091766_____

Device Name: _ Clearview® Exact PBP2a Test_____

Indications for Use:

The Clearview® Exact PBP2a Test is a qualitative, *in vitro* immunochromatographic assay for the detection of penicillin-binding protein 2a (PBP2a) in isolates identified as *Staphylococcus aureus*, as an aid in detecting methicillin-resistant *Staphylococcus aureus* (MRSA). The Clearview® Exact PBP2a Test is not intended to diagnose MRSA nor to guide or monitor treatment for MRSA infections.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie M. Poole

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 091766