



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 13 2007

Ms. Anne Jepson
Manager, Clinical Affairs
Binax, Inc.
Inverness Medical Innovations, Inc.
10 Southgate Road
Scarborough, ME 04074

Re: k061542
Evaluation of Automatic Class III Designation
Binax NOW[®] Malaria Test
Regulation Number: 21 CFR 866.3402
Classification: II
Product Code: OAX

Dear Ms. Jepson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Binax NOW[®] Malaria Test as a prescription device under 21 CFR Part 801.109 that is intended for the qualitative detection of *Plasmodium* antigens circulating in human venous and capillary EDTA whole blood of individuals with signs and symptoms of malarial infection. The test targets the histidine-rich protein II (HRP2) antigen specific to *Plasmodium falciparum* and a pan-malarial antigen, common to all four malaria species capable of infecting humans - *P. falciparum*, *P. vivax*, *P. ovale*, and *P. malariae*. It is intended to aid in the rapid diagnosis of human malaria infections and to aid in the differential diagnosis of *Plasmodium falciparum* infections from other less virulent malarial infections. Negative results must be confirmed by thin/thick smear microscopy.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Binax NOW[®] Malaria Test, and substantially equivalent devices of this generic type into class II under the generic name, *Plasmodium* species antigen detection assays. This order also identifies the special controls applicable to this device if put into class II.

FDA identifies this generic type of device as:

21 CFR 866.3402 *Plasmodium* species antigen detection assay. It is identified as a device that that employs antibodies for the detection of specific antigens to *Plasmodium* species

including; histidine-rich protein-II (HRP2) specific antigens, and pan-malarial antigens in human whole blood.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device.

On February 22, 2007, FDA issued an order classifying the NOW[®] Malaria Test into class III because it was not substantially equivalent to a class I or class II device. On March 26, 2007, FDA filed your petition requesting classification of the Binax NOW[®] Malaria Test into class II. The petition was submitted under section 513(f)(2) of the act.

In order to classify the Binax NOW[®] Malaria Test into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA has determined that the Binax NOW[®] Malaria Test intended for the qualitative detection of *Plasmodium* antigens circulating in human venous and capillary EDTA whole blood of individuals with signs and symptoms of malarial infection can be classified in class II with the establishment of special controls. Negative results must be confirmed by thin/thick smear microscopy, and therefore can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

There are no known **direct** risks to an individual's health. However, failure of the test to perform as indicated or an error in interpretation of results may lead to improper patient management and inappropriate public health responses. Therefore, use of test results to establish a treatment regimen without consideration of other clinical factors, and without confirmation of negative results via another diagnostic method, could pose a risk. Falsely negative results may lead to delays in providing, or even failure to provide, definitive diagnosis and appropriate treatment. False negative test results may place individuals, especially those infected with *P. falciparum*, at risk by not receiving appropriate therapy. There are no clinical features that distinguish *P. falciparum* infection from infection by the other less virulent *Plasmodium* species (*P. vivax*, *P. ovale*, and *P. malariae*). The test is used to aid in the differentiation of *P. falciparum* from the other species. Therefore, false test results could contribute to improper patient management, with respect to the treatment of *P. falciparum* and / or malaria in general. For example, a false negative test could result in treatment for another endemic parasitic disease with similar symptoms that is non-effective against *Plasmodium* species. Additionally, missed infections caused by *P. vivax* and *P. ovale* are problematic since the hypnozoite forms of these two species can remain dormant in the liver and cause relapsing infections. False negative results in pregnant women and newborns, or other unique populations, may entail additional risk due to limited treatment opportunities (e.g., for preventing consequences of congenital infection). Malarial infection in pregnant women can lead to severe disease in the mother, premature delivery and/or delivery of low birth-weight infants.

In addition to the general controls of the act, *Plasmodium* species antigen detection assays are subject to the following special controls: "Class II Special Controls Guidance Document: *Plasmodium* species antigen detection assays". Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the *Plasmodium* species antigen detection assay they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order. If you have any questions concerning this classification order, please contact Peter L. Summers M.S., at 240-276-0771.

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
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