DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 8 2003

Ms. Kate Wersin
Regulatory Affairs Officer
PANBIO Limited
116 Lutwyche Road
Windsor
Brisbane, Queensland
Australia

Re: K031703
Evaluation of Automatic Class III Designation
West Nile Virus IgM Capture ELISA Assay
Regulation Number: 21 CFR 866.3940
Classification: II
Product Code: NOP

Dear Ms.Wersin:

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 West Nile Virus IgM Capture ELISA Assay that is intended for use for the qualitative detection of IgM antibodies to West Nile Virus in serum as an aid in the clinical laboratory diagnosis of West Nile Virus infection in patients with clinical symptoms consistent with meningitis/encephalitis. The PANBIO West Nile Virus IgM Capture ELISA results are presumptive. Positive results must be confirmed by Plaque Reduction Neutralization Test (PRNT), or by using the current CDC guidelines for diagnosis of this disease. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the West Nile Virus IgM Capture ELISA Assay, and substantially equivalent devices of this generic type into class II under the generic name, West Nile Virus, Serological Reagents. This order also identifies the special controls applicable to this device.

FDA identifies this generic type of device as:

21 CFR 866.3940 –West Nile Virus, Serological Reagents. West Nile Virus serological reagents are devices that consist of antigens and antisera for the detection of anti-West Nile Virus IgM antibodies, in human serum, from individuals that have signs and symptoms consistent with viral meningitis/encephalitis. The detection aids in the clinical laboratory diagnosis of viral meningitis/encephalitis caused by West Nile Virus.

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 type. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device type, FDA must publish a notice in the **Federal Register** classifying the device type.

On July 3, 2003, FDA filed your petition requesting classification of the West Nile Virus IgM Capture ELISA Assay into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on June 20, 2003, automatically classifying the West Nile Virus IgM Capture ELISA Assay in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the West Nile Virus IgM Capture ELISA Assay 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 and the scientific literature, FDA has determined that the West Nile Virus IgM Capture ELISA Assay intended for qualitative detection of IgM antibodies to West Nile Virus in serum as an aid in the clinical laboratory diagnosis of West Nile Virus infection in patients with clinical symptoms consistent with meningitis/encephalitis. The PANBIO West Nile Virus IgM Capture ELISA results are presumptive. Positive results must be confirmed by Plaque Reduction Neutralization Test (PRNT), or by using the current CDC guidelines for diagnosis of this disease 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 type.

There are no known *direct* risks to patient health. However, failure of the test to perform as indicated or error in interpretation of results may lead to improper patient management. Therefore use of assay results to adjust a treatment regimen without consideration of other clinical factors could pose a risk. Falsely negative measurements could result in an incorrect determination that the patient is not infected with West Nile Virus and may lead to incorrect decisions about patient management and treatment. Falsely positive measurements could result in an incorrect determination that a patient is infected with West Nile Virus. This information could mislead the health care provider causing an inappropriate work-up and/or incorrect treatment.

FDA has identified the risks to health generally associated with the use of the West Nile Virus IgM Capture ELISA Assay addressed in the special controls document, "Class II Special Control Guidance Document: West Nile Virus Serological Assays". The measures recommended to mitigate these identified risks are given in this guidance document, and aids the manufacturer in establishing performance characteristics and appropriate labeling. The premarket notification should describe the risk analysis method. These controls include labeling and performance characteristics such as clinical and analytical information.

In addition to the general controls of the act, the West Nile Virus IgM Capture ELISA Assay is subject to the following special controls: "Class II Special Control Guidance Document: West Nile Virus, Serological 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 type must submit to FDA a premarket notification submission containing information on the device they intend to market and receive a determination of substantial equivalence prior to marketing the device.

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 Sally A. Hojvat, Ph.D., at 301 594-2096.

Sincerely,

S. Gutman

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