DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Estela I. Raychaudhuri
President
InBios International Inc.
562 1st Ave. South, Suite 600
Seattle, WA 98104

OCT 05 2011

Re: K100534 InBios DENV Detect IgM Capture ELISA
Evaluation of Automatic Class III Designation
Regulation Number:
Classification: II
Product Code: OSU

Dear Estela I. Raychaudhuri:

This acknowledges our letter of April 8, 2011 to the same effect.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the InBios DENV Detect IgM Capture ELISA is a prescription device under 21 CFR Part 801.109 that is indicated for the qualitative detection of IgM antibodies to DEN recombinant antigens (DENRA) in serum for the presumptive clinical laboratory diagnosis of Dengue virus infection. The assay is intended for use only in patients with clinical symptoms consistent with either dengue fever or dengue hemorrhagic fever. 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 InBios DENV Detect IgM Capture ELISA, and substantially equivalent devices of this generic type into class II under the generic name, Dengue serological reagents.

FDA identifies this generic type of device as:

21 CFR 866.3945 – Dengue virus serological reagents. Dengue virus serological reagents are devices that consist of antigens and antibodies for the detection of dengue virus and dengue antibodies in individuals who have signs and symptoms of dengue fever or dengue hemorrhagic fever. The detection aids in the clinical laboratory diagnosis of dengue fever or dengue hemorrhagic fever caused by dengue 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, with in 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 type.

On October 20, 2010, FDA filed your petition requesting classification of the InBios DENV Detect IgM Capture ELISA 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 October 8, 2010 automatically classifying the InBios DENV Detect IgM Capture ELISA 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, nor which was subsequently reclassified into class I or class II. In order to classify the InBios DENV Detect IgM Capture ELISA 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 InBios DENV Detect IgM Capture ELISA indicated for the qualitative detection of IgM antibodies to DEN recombinant antigens (DENRA) in serum for the presumptive clinical laboratory diagnosis of Dengue virus infection. The assay is intended for use only in patients with clinical symptoms consistent with either dengue fever or dengue hemorrhagic fever. 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 for class II. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

FDA has identified the following risks to health associated with the use of dengue serological reagents. Failure of dengue serological detection devices to perform as indicated or an error in interpretation of the results, may lead to misdiagnosis with significant implications. In the setting of individual patient diagnosis this may lead to improper management of a specific individual; for example, a false negative result test result may lead to inappropriate antibiotic use, or a false positive

result may lead to a delay in finding the true diagnosis. Perhaps more importantly, failure to identify the cause of a dengue outbreak due to false negative results may allow dengue disease to spread easier because mosquito control was not initiated sooner; a false positive result during a outbreak investigation may lead to unnecessary mosquito control measures to eradicate or reduce the disease vector. The measures FDA recommends to mitigate these risks are described in the guidance document entitled "Class II Special Controls Guidance Document: Serological Reagents for the Diagnosis of Dengue Infection," which included recommendations for evaluating assay performance and labeling.

In addition to the general controls of the act, the InBios DENV Detect IgM Capture ELISA is subject to the following special controls: the guidance document entitled, "Class II Special Controls Guidance Document: Serological Reagents for the Diagnosis of Dengue Infection" to address the specific risks to health associated with this device type. 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 type. 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 of the act. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the dengue serological 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 your device as described in the de novo, 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 301-796-6205.

Sincerely yours,

Alberto Gutiérrez, Ph.D.
Director
Office of *In Vitro* Diagnostic Devices
Evaluation and Safety
Center for Devices and Radiological Health