



Centers for Disease Control and Prevention
c/o CAPT Hye-Joo Kim, Pharm.D.
Associate Director for Regulatory Affairs
1600 Clifton Road, MS-C18
Atlanta, GA 30333

MAY 24 2012

Re: K113336
CDC DENV-1-4 Real-Time RT-PCR Assay
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 866.3946
Regulation Name: Dengue virus Nucleic Acid Amplification Test Reagents
Regulatory Classification: Class II
Product Code: OZB, NSU
Dated: March 9, 2012
Received: March 12, 2012

Dear CAPT Kim:

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 CDC DENV-1-4 Real-Time RT-PCR Assay that is indicated for the diagnosis of dengue in serum or plasma collected from patients with signs and symptoms consistent with dengue (mild or severe); for identification of dengue virus serotypes 1, 2, 3 or 4 from viral RNA in serum or plasma (sodium citrate) collected from human patients with dengue. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the CDC DENV-1-4 Real-Time RT-PCR Assay and substantially equivalent devices of this generic type, into class II under the generic name, Dengue virus nucleic acid amplification test reagents.

FDA identifies this generic type of device as:

Dengue virus nucleic acid amplification test reagents. Dengue virus nucleic acid amplification test reagents are devices that consist of primers, probes, enzymes, and controls for amplification and detection of Dengue virus serotypes 1, 2, 3, or 4 from viral RNA in human serum and plasma from individuals who have signs and symptoms consistent with dengue (mild or severe).

The identification of Dengue virus serotypes 1, 2, 3 or 4 in human serum and plasma (sodium citrate) collected from human patients with dengue provides epidemiologic information for surveillance of circulating dengue viruses.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C 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 FD&C 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 FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C 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 type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on February 24, 2012 automatically classifying the CDC DENV-1-4 Real-Time RT-PCR 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, nor which was subsequently reclassified into class I or class II. On March 12, 2012, FDA filed your petition requesting classification of the CDC DENV 1-4 Real-Time RT-PCR Assay into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the CDC DENV-1-4 Real-Time RT-PCR Assay into class 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 CDC DENV-1-4 Real-Time RT-PCR Assay indicated for the diagnosis of dengue in serum or plasma collected from patients with signs and symptoms consistent with dengue (mild or severe) and for the identification of dengue virus serotypes 1, 2, 3 or 4 from viral RNA in serum or plasma (sodium citrate) collected from human patients with dengue 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 virus nucleic acid amplification test reagents. Failure of Dengue virus nucleic acid amplification test reagents to perform as indicated or an error in interpretation of the results may lead to misdiagnosis with significant implications on patient management. A false positive test result for an individual may lead to unnecessary treatment and possibly a less thorough laboratory evaluation for the true cause of illness; in the setting of an outbreak investigation, a false positive result may lead to unnecessary initiation of mosquito vector control measures. A false negative result may lead to inappropriate use of antibiotics or not being treated with appropriate intravenous fluids or platelet transfusion, or a false negative result may lead to delay in recognizing the cause of the outbreak and the initiation of adequate mosquito vector control measures. The measures FDA recommends to mitigate this risk are described in the guidance document entitled “Class II Special Controls Guidance Document: Dengue virus nucleic acid amplification test reagents,” which includes recommendations for the device design, performance validation and labeling.

In addition to the general controls of the FD&C Act, the Dengue virus nucleic acid amplification test reagents is subject to the following special controls: the guidance document entitled “Class II Special Controls Guidance Document: Dengue virus nucleic acid amplification test reagents.” Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C 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 FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Dengue virus nucleic acid amplification assay reagents they intend to market prior to marketing the device and receive clearance to market from FDA.

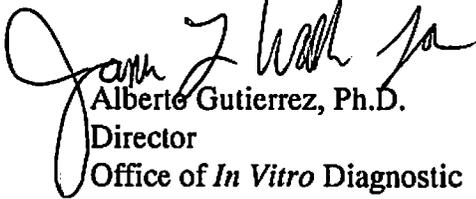
A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for 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 FD&C Act and the special controls identified in this order.

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If you have any questions concerning this classification order, please contact Beena Puri, Ph.D. at (301)-796-6202.

Sincerely yours,



Alberto Gutierrez, Ph.D.

Director

Office of *In Vitro* Diagnostic
Device Evaluation and Safety
Center for Devices and
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