DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Hye-Joo Kim, Pharm.D.
Deputy Chief of Regulatory Affairs
National Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, MS-C12
Atlanta, GA 30333

Re: k060159, Evaluation of Automatic Class III Designation
Influenza A/H5 (Asian Lineage) Virus Real-time RT-PCR Primer and Probe Set
Regulation Number: 21 CFR 866.3332
Classification: Class II
Product Code: NXD

Dear Ms. Kim:

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 Influenza A/H5 (Asian Lineage) Virus Real-time RT-PCR Primer and Probe Set. This device is intended for the in vitro qualitative detection of Influenza A/H5 (Asian lineage) virus RNA either directly in patient respiratory specimens or in viral cultures for the presumptive laboratory identification of Influenza A/H5 (Asian lineage) virus. Testing with the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set should be used in conjunction with other laboratory testing and clinical observations for the following indications:

1. Providing epidemiological information for the surveillance of human infection with influenza A/H5 (Asian lineage) virus

2. Identifying patients who may be infected with influenza A/H5 (Asian lineage) virus based on clinical and epidemiological risk factors.

The definitive identification of influenza A/H5 (Asian lineage) either directly from patient specimens or from viral cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Influenza A/H5 (Asian Lineage) Virus Real-time RT-PCR Primer and Probe Set into class II under the generic name, Reagents for Detection of Specific Novel Influenza A Viruses. This order also identifies the special controls applicable to this device, and substantially equivalent devices of this generic type.

FDA identifies this generic type of device as:

21 CFR 866.3332 Reagents for detection of specific novel influenza A viruses. Reagents for detection of specific novel influenza A viruses are devices that are intended for use in a nucleic acid amplification test to directly detect specific virus RNA in human respiratory specimens or viral cultures. Detection of specific virus RNA aids in the diagnosis of influenza caused by specific novel influenza A viruses in patients with clinical risk of infection with these viruses, and also aids in the presumptive laboratory identification of specific novel influenza A viruses to provide epidemiological information on influenza. These reagents include primers, probes, and specific influenza A virus controls.

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 type. 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 January 27, 2006, FDA filed your petition requesting classification of the Influenza A/H5 (Asian Lineage) Virus Real-time RT-PCR Primer and Probe Set 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 had issued an order on January 26 affirming that the Influenza A/H5 (Asian Lineage) Virus Real-time RT-PCR Primer and Probe Set was classified in class III according to statute, because it was not substantially equivalent to a class I or class II device.

In order to classify the Influenza A/H5 (Asian Lineage) Virus Real-time RT-PCR Primer and Probe Set 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 classification petition, FDA has determined that the Influenza A/H5 (Asian lineage) Virus Real-time RT-PCR Primer and Probe Set can be classified in class II with the establishment of special controls.

FDA has identified several risks associated with use of reagents for detection of specific novel influenza A viruses. Failure of testing with reagents for detection of specific novel influenza A viruses to correctly identify a specific novel influenza A virus, or failure to properly interpret test results obtained with these reagents, could lead to incorrect patient management decisions and inappropriate public health responses. Also, the use of reagents for detection of specific novel influenza A viruses without appropriate biosafety equipment and containment could result in laboratory-acquired infection and viral reassortment.

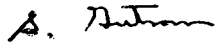
The special controls that are established to mitigate these risks are the guidance document, "Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses," which contains recommendations for the contents of premarket notification submissions including performance testing, labeling, and postmarket data collection and analysis; and the limitation of distribution of these reagents to laboratories with (i) experienced personnel who have training in standardized molecular testing procedures and expertise in viral diagnosis, and (ii) appropriate biosafety equipment and containment. FDA believes that these special controls, along with the general controls of the act, will be sufficient to provide reasonable assurance of the safety and effectiveness of reagents for detection of specific novel influenza A viruses.

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 type is not exempt from the premarket notification requirements. Thus, persons who intend to market this type device must submit to FDA a premarket notification submission containing information on the reagents for detection of specific novel influenza A viruses they intend to market 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 Claudia Gaffey at 240-276-0496.

Sincerely yours,



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