DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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JAN 20 2012

Re: K112394
STRATIFY JCV™ Antibody ELISA
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 866.3336
Regulation Name: John Cunningham Virus serological reagents
Regulatory Classification: Class II
Product Code: OYP
Dated: January 5, 2012
Received: January 6, 2012

Dear Ms. Viviani:

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 STRATIFY JCV™ Antibody ELISA that is indicated for use in conjunction with other clinical data, in multiple sclerosis and Crohn's disease patients receiving natalizumab therapy, as an aid in risk stratification for progressive multifocal leukoencephalopathy development. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the STRATIFY JCV™ Antibody ELISA, and substantially equivalent devices of this generic type, into class II under the generic name, John Cunningham Virus serological reagents.

FDA identifies this generic type of device as:
John Cunningham Virus serological reagents. Identification. John Cunningham Virus serological reagents are devices that consist of antigens and antisera used in serological assays to identify antibodies to John Cunningham Virus in serum and plasma. The identification aids in the risk stratification for the development of progressive multifocal leukoencephalopathy in multiple sclerosis and Crohn's disease patients undergoing natalizumab therapy. These devices are for adjunctive use, in the context of other clinical risk factors for the development of progressive multifocal leukoencephalopathy.

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 December 22, 2011 automatically classifying the STRATIFY JCV™ Antibody 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. On January 6, 2012, FDA filed your petition requesting classification of the STRATIFY JCV™ Antibody ELISA into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the STRATIFY JCV™ Antibody 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 STRATIFY JCV™ Antibody ELISA indicated for use in conjunction with other clinical data, in multiple sclerosis and Crohn's disease patients receiving natalizumab therapy, as an aid in risk stratification for progressive multifocal leukoencephalopathy development 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 John Cunningham Virus serological reagents. Failure of the John Cunningham Virus serological reagents to perform as indicated or an error in the interpretation of the results may lead improper patient management. False positive results may lead a physician and patient to elect not to use natalizumab therapy, due to perceived increased risk of developing progressive multifocal leukoencephalopathy. The patient may have a reduced quality of life due to continuing multiple sclerosis or Crohn's disease symptoms. False negative results may lead to an under-estimation of the patients risk for developing progressive multifocal leukoencephalopathy. This is because prior infection with John Cunningham Virus is a known precursor of progressive multifocal leukoencephalopathy development. If the patient receives

a false negative result they would be at a higher than the anticipated risk of developing progressive multifocal leukoencephalopathy. The physician's choice for using natalizumab therapy may predispose the patient to developing progressive multifocal leukoencephalopathy. The measures FDA recommends to mitigate this risk are described in the guidance document entitled "Class II Special Controls Guidance Document: John Cunningham Virus Serological Reagents," which includes recommendations for the device design, performance validation and labeling.

In addition to the general controls of the FD&C Act, the John Cunningham Virus serological reagents is subject to the following special controls: the guidance document entitled "Class II Special Controls Guidance Document: John Cunningham Virus Serological 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 John Cunningham Virus serological 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.

If you have any questions concerning this classification order, please contact Haja Sittana El Mubarak, Ph.D. at 301-796-6193.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostic
Device Evaluation and Safety
Center for Devices and
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