DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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APR 3 0 2012

Larry Rea
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Re: k113358
Portrait Toxigenic *C. difficile* Assay
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 866.3130
Regulation Name: *Clostridium difficile* toxin gene amplification assay
Regulatory Classification: Class II
Product Code: OZN
Dated: February 29, 2012
Received: March 2, 2012

Dear Mr. Rea:

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 Portrait Toxigenic *C. difficile* Assay, a prescription device under 21 CFR Part 801.109 that is indicated for the detection of toxigenic *Clostridium difficile* in human fecal samples collected from patients suspected of having *Clostridium difficile* infection (CDI). The test utilizes automated blocked primer enabled helicase-dependent amplification (bpHDA) to detect toxin gene sequences associated with toxin producing *C. difficile*. The Portrait Toxigenic *C. difficile* Assay is intended as an aid in the diagnosis of CDI. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Portrait Toxigenic *C. difficile* Assay, and substantially equivalent devices of this generic type, into class II under the generic name, *Clostridium difficile* toxin gene amplification assay.

FDA identifies this generic type of device as: A *Clostridium difficile* toxin gene amplification assay is a device that consists of reagents for the amplification and detection of target sequences in *Clostridium difficile* toxin genes in fecal specimens from patients suspected of having *Clostridium difficile* infection (CDI). The detection of clostridial toxin genes, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of CDI caused by *Clostridium difficile*.

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 3, 2012 automatically classifying the Portrait Toxigenic *C. difficile* 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 2, 2012, FDA filed your petition requesting classification of the Portrait Toxigenic *C. difficile* Assay into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Portrait Toxigenic *C. difficile* 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 Portrait Toxigenic *C. difficile* Assay is indicated for the detection of toxigenic *Clostridium difficile* in human fecal samples collected from patients suspected of having *Clostridium difficile* infection (CDI). The test utilizes automated blocked primer enabled helicase-dependent amplification (bpHDA) to detect toxin gene sequences associated with toxin producing *C. difficile*. The Portrait Toxigenic *C. difficile* Assay is intended as an aid in the diagnosis of CDI and 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.

Table - Potential Risks and Mitigations

Identified Potential Risk	Recommended Mitigation Measure
A false positive test result for an individual may lead to inappropriate use of antibiotics for treatment.	Kit includes quality control material and instructions for use.
A false negative test result for an individual may lead to a potential delay in treatment.	Kit includes quality control material and instructions for use.
Failure of the test to perform properly.	Product Labeling provides instructions for use and Limitations of the assay
Failure to properly interpret the test results.	Product labeling describes interpretation of results.

In addition to the general controls of the FD&C Act, the *Clostridium difficile* toxin gene amplification assay is subject to the following special controls: the guidance document entitled, "Class II Special controls Guidance Document: Toxin Gene Amplification Assays for the Detection of *Clostridium difficile*". 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 *Clostridium difficile* toxin gene amplification 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 FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Marian Heyliger, MS, at 301 796 6199.

Sincerely yours,

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