



Food and Drug Administration
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Luminex Molecular Diagnostics
c/o Lubna Syed
Director for Regulatory Affairs
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JAN 14 2013

Re: k121454 – Order for Granting the Petition for De Novo Classification/Establishing Special Controls
xTAG® Gastrointestinal Pathogen Panel (GPP)
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal microorganism multiplex nucleic acid-based assay
Regulatory Classification: Class II
Product Code: PCH, NSU, JJH
Dated: January 10, 2013
Received: January 11, 2013

Dear Ms. Syed:

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 for (de novo) classification of the xTAG® Gastrointestinal Pathogen Panel (GPP) that is indicated for the simultaneous qualitative detection and identification of multiple viral, parasitic, and bacterial nucleic acids in human stool specimens from individuals with signs and symptoms of infectious colitis or gastroenteritis. FDA concludes that this device should be classified into class II. This order, therefore, classifies the xTAG® Gastrointestinal Pathogen Panel (GPP) into class II under the generic name “Gastrointestinal microorganism multiplex nucleic acid-based assay.”

FDA identifies this generic type of device as: A gastrointestinal microorganism multiplex nucleic acid-based assay is a qualitative *in vitro* diagnostic device intended to simultaneously detect and identify multiple gastrointestinal microbial nucleic acids extracted from human stool specimens. The device detects specific nucleic acid sequences for organism identification as well as for determining the presence of toxin genes. The detection and identification of a specific gastrointestinal microbial nucleic acid from individuals exhibiting signs and symptoms of gastrointestinal infection aids in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation and other laboratory findings. A gastrointestinal microorganism multiplex nucleic acid-based assay also aids in the detection and identification of acute gastroenteritis in the context of outbreaks.

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) for a type of device that has not been previously classified 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 by order classify the device, which 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** announcing the classification.

In accordance with section 513(f)(1) and 513(i) of the FD&C Act, FDA issued an order on January 3, 2013 finding the xTAG[®] Gastrointestinal Pathogen Panel (GPP) not substantially equivalent to any device within a type that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976 or that was subsequently reclassified into class I or class II, which means this device is automatically in class III under section 513(f)(1). On January 11, 2013, FDA filed your petition requesting classification of the xTAG[®] Gastrointestinal Pathogen Panel (GPP) into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the xTAG[®] Gastrointestinal Pathogen Panel (GPP) 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 xTAG[®] Gastrointestinal Pathogen Panel (GPP), which is indicated for the simultaneous qualitative detection and identification of multiple viral, parasitic, and bacterial nucleic acids in human stool specimens from individuals with signs and symptoms of infectious colitis or gastroenteritis, can be classified in class II with the establishment of special controls for this type of device. FDA believes that the special controls identified later in this order, along with applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type.

FDA has identified the risks to health associated with the use of xTAG[®] Gastrointestinal Pathogen Panel (GPP) that require special controls to be the following: failure of the device to detect and identify a targeted organism when such organism is present in the specimen (i.e., false negative test result for presence of organism) and detection of the targeted microorganism when such organism is not present in the specimen (i.e., false positive test result for presence of organism), both of which can lead to individual and/or public health consequences, and failure to correctly interpret test results.

Failure of the device to detect and identify a targeted organism when such organism is present in the specimen (a false negative test result) may lead to a delay in finding the true cause of the gastrointestinal infection, additional diagnostic tests, and unnecessary treatment or to inappropriate antibiotic use. For certain microorganisms detected by the device, failure of detection may contribute to incorrect patient management to prevent transmission of infection, or delay recognition of an outbreak. An incorrect positive test result (a false positive test result) also may lead to unnecessary or ineffective antibiotic therapy and delay in determining the true cause of the patient's illness, which for some microorganisms may lead to a more serious infection. Additionally, in the context of public health, a false positive test result may lead to misallocation of resources used for disease surveillance and prevention.

Failure to correctly interpret test results in the context of other clinical and laboratory findings may lead to inappropriate or delayed treatment. For example, a microorganism present as a colonizer may be correctly detected, but not be the true cause of illness. Although this identical risk would be present from use of any microbiological assay in this setting, simultaneous testing of multiple analytes in a multiplex assay may be more likely to detect an unanticipated colonizer that might not be tested for individually.

Special controls are necessary to address the risks posed by this device and to provide a reasonable assurance of safety and effectiveness. The special controls here include mitigation measures relating to design characteristics, device specific performance characteristics, and device specific labeling. More specific information on these mitigation measures will be set out in the special controls guideline entitled “Class II Special Controls Guideline: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens.” Persons who intend to market devices of this type must either (1) comply with the particular mitigation measures set forth in the special controls guideline or (2) use alternative mitigation measures, but demonstrate to the Agency’s satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. Furthermore, prior to marketing, firms must obtain FDA clearance of a premarket notification submission demonstrating substantial equivalence to another device within this type prior to marketing any other devices of this type.

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 market your device 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 Andrew Grove, Ph.D. at (301) 796-6198.

Sincerely yours,

Donald J. St Pierre

Digitally signed by Donald J. St Pierre
DN: c=US, ou=U.S. Government, ou=FDA,
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