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APR 26 2006

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: k050007
Evaluation of Automatic Class III Designation
PhiCal™ Fecal Calprotectin Immunoassay
Regulation Number: 21 CFR 866.5180
Classification: Class II
Product Code: NXO

Dear Dr. Hanaway:

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 PhiCal™ Fecal Calprotectin Immunoassay that is a quantitative ELISA for measuring, in human stool, concentrations of fecal calprotectin, a neutrophilic protein that is a marker of mucosal inflammation. The PhiCal™ test can be used as an *in vitro* diagnostic to aid in the diagnosis of inflammatory bowel diseases (IBD): Crohn's disease and ulcerative colitis, and to differentiate IBD from irritable bowel syndrome (IBS) when used in conjunction with other diagnostic testing and the total clinical picture. FDA concludes that this device should be classified into class II. This order, therefore, classifies the PhiCal™ Fecal Calprotectin Immunoassay into class II under the generic name, fecal calprotectin immunological test system. 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 866.5180 Fecal calprotectin immunological test system. A fecal calprotectin immunological test system is an *in vitro* device that consists of reagents used to quantitatively measure, by immunochemical techniques, fecal calprotectin in human stool specimens. The device is intended for *in vitro* diagnostic use as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome.

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, 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 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 March 23, 2006, FDA filed your petition requesting classification of the PhiCal™ Fecal Calprotectin Immunoassay 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 issued an order on March 21, 2006, affirming that the PhiCal™ Fecal Calprotectin Immunoassay 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 PhiCal™ Fecal Calprotectin Immunoassay 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 PhiCal™ Fecal Calprotectin Immunoassay can be classified in class II with the establishment of special controls.

FDA has identified no direct risks to health related to use of fecal calprotectin immunological test systems. However, failure of the assay to perform as indicated could lead to inappropriate risk assessment and improper management of patients with IBD. Specifically, a falsely low fecal calprotectin could result in a determination that the patient may not have IBD, which could delay appropriate treatment or that the patient may have IBS which has significantly different clinical management. A falsely high fecal calprotectin could result in a determination that the patient may have IBD which could lead to unnecessary evaluation and testing or inappropriate treatment decisions. Use of assay results without consideration of other diagnostic testing and clinical assessment could also pose a risk. The measures FDA recommends to mitigate these risks are described in the guidance document, "Class II Special Controls Guidance Document: Fecal Calprotectin Immunological

Test Systems”, which includes recommendations for performance validation and labeling.

In addition to the general controls of the act, fecal calprotectin immunological test systems are subject to the following special controls: “Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems”. 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. 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 device type must submit to FDA a premarket notification submission containing information on the fecal calprotectin immunological test system 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 Deborah Moore at (240) 276-0493.

Sincerely yours,



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