DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

JAN - 4 2012

R-Biopharm AG
c/o Lehnus and Associates Consulting
150 Cherry Lane Rd.
East Stroudsburg, PA 18301
United States

Re: K093295
RIDASCREEN® Norovirus 3rd Generation
Regulation Number: 21 CFR 866.3395
Dated: February 2, 2011
Received: February 9, 2011

Dear Dr. Lehnus:

This letter corrects our previous letter of February 23, 2011.

In the February 23, 2011, letter, FDA concluded that the RIDASCREEN® Norovirus 3rd Generation EIA, indicated for the detection of selected genogroup I (GI.1, GI.2, GI.3, GI.4, GI.7) and genogroup II (GII 1, GII.2, GII.3, GII.4, GII.5, GII.6, GII.7, GII.8, GII.10, GII.12, GII.13, GII.14, GII.17) norovirus strains in human feces as an aid in investigating the cause of acute gastroenteritis outbreaks, was substantially equivalent to devices of this generic type, should be classified into class II. The letter, classified the RIDASCREEN® Norovirus 3rd Generation EIA, as substantially equivalent devices of this generic type into class II under the generic name, Norovirus serological reagents.

In the letter FDA identified this generic type of device as:

21 CFR 866.3395 Norovirus serological reagents. Norovirus serological reagents are devices that consist of antigens and antisera used in serological tests to detect the presence of norovirus antigens in fecal samples. These devices aid in the diagnosis of norovirus infection in the setting of an individual patient with symptoms of acute gastroenteritis and/or aid in the identification of norovirus as the etiology of an outbreak of acute gastroenteritis in the setting of epidemiologically linked patients with symptoms of acute gastroenteritis.

On further review of this application we have revised the wording of the generic type of device to the following:

21 CFR 866.3395 Norovirus serological reagents. Identification. Norovirus serological reagents. Norovirus serological reagents are devices that consist of antigens and antisera

used in serological tests to detect the presence of norovirus antigens in fecal samples. These devices aid in the diagnosis of norovirus infection in the setting of an individual patient with symptoms of acute gastroenteritis when the individual patient is epidemiologically linked to other patients with symptoms of acute gastroenteritis and/or aid in the identification of norovirus as the etiology of an outbreak of acute gastroenteritis in the setting of epidemiologically linked patients with symptoms of acute gastroenteritis.

No action is required on your part in response to this letter. A notice announcing this classification order with the revised language above will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HF A-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.

If you have any questions regarding this letter, please contact Steven Gitterman, M.D., Ph.D., Division of Microbiology Devices, at 301-796-6696, or for general questions please contact the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

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