DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

RESONANCE HEALTH SERVICES
% MR. GREG HOLLAND
REGULATORY SPECIALISTS, INC.
3722 AVE. SAUSALITO
IRVINE, CA 92606

JAN 23 2013

Re: K124065 – Order for Granting the Petition of De Novo Classification/Establishing Special Controls
FerriScan R2-MRI Analysis System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 892.1001
Regulation Name: Liver Iron Concentration Imaging Companion Diagnostic for Deferasirox
Regulatory Classification: Class II
Product Code: PCS
Dated: December 20, 2012
Received: December 21, 2012

Dear Mr. Holland:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the FerriScan R2-MRI Analysis System, a prescription device under 21 CFR Part 801.109 that is indicated to measure liver iron concentration to aid in the identification and monitoring of non-transfusion-dependent thalassemia patients receiving therapy with deferasirox. FDA concludes that this device should be classified into class II. This order, therefore, classifies the FerriScan R2-MRI Analysis System into class II under the generic name, liver iron concentration imaging companion diagnostic for deferasirox.

FDA identifies this generic type of device as:
Liver iron concentration imaging companion diagnostic for deferasirox

The liver iron concentration imaging companion diagnostic for deferasirox is an image processing device intended to aid in the identification and monitoring of non-transfusion-dependent thalassemia patients receiving therapy with deferasirox. The device calculates a numeric value for liver iron concentration based on magnetic resonance images acquired under controlled conditions. The calculated numeric value is used to assess the need for deferasirox treatment and for monitoring treatment in patients with non-transfusion-dependent thalassemia. The liver iron concentration imaging companion diagnostic for deferasirox is essential to the safe and effective use of deferasirox in patients with non-transfusion-dependent thalassemia.

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a type of device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the type of device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 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** announcing the classification.

On December 21, 2012, FDA received your *de novo* requesting classification of the FerriScan R2-MRI Analysis System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the FerriScan R2-MRI Analysis System 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 *de novo* request FDA has determined that the FerriScan R2-MRI Analysis System indicated for:

> The FerriScan R2-MRI Analysis System is intended to measure liver iron concentration to aid in the identification and monitoring of non-transfusion-dependent thalassemia patients receiving therapy with deferasirox.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II (special) controls identified later in this order, along with the applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type.

Table - Potential Risks and Mitigations

Identified Potential Risk	**Required Mitigation Measure**
False positive result	Labeling must specify instructions for acceptance testing of images prior to processing. Labeling must specify data processing quality assurance protocols. Nonclinical and clinical performance testing must be included in the premarket notification submission demonstrating the bias, precision, repeatability, and reproducibility of liver iron concentration measurements.
False negative result	Labeling must specify instructions for acceptance testing of images prior to processing.

Identified Potential Risk	Required Mitigation Measure
	Labeling must specify data processing quality assurance protocols. Nonclinical and clinical performance testing must be included in the premarket notification submission demonstrating the bias, precision, repeatability, and reproducibility of liver iron concentration measurements.
Sensitivity and specificity are not suitable for clinical decision making	Labeling must specify the sensitivity and specificity of liver iron concentration measurements. Nonclinical and clinical performance testing must be included in the premarket notification submission demonstrating the bias, precision, repeatability, and reproducibility of liver iron concentration measurements.

In addition to the general controls of the FD&C Act, the Liver Iron Concentration Imaging Companion Diagnostic for Deferasirox is subject to the following special controls:

(1) Labeling must specify instructions for acceptance testing of images prior to processing.
(2) Labeling must specify data processing quality assurance protocols.
(3) Labeling must specify the sensitivity and specificity of liver iron concentration measurements.
(4) Nonclinical and clinical performance testing must be included in the premarket notification submission demonstrating the bias, precision, repeatability, and reproducibility of liver iron concentration measurements.

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 liver iron concentration imaging companion diagnostic for deferasirox they intend to market and receive clearance to market from FDA 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 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 Daniel Krainak at 301-796-0478.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health