



July 8, 2025

Resonance Health Services
% Mr. Greg Holland
Regulatory Specialists, Inc.
3722 Sausalito Ave.
Irvine, CA 92606

Re: K124065 (DEN130012)
Trade/Device Name: FerriScan R2-MRI Analysis System
Regulation Number: 21 CFR 892.1001
Regulation Name: Liver iron concentration imaging companion diagnostic for deferasirox
Regulatory Class: Class II
Product Code: PCS
Dated: December 20, 2012
Received: December 21, 2012

Dear Mr. Holland:

This letter corrects the classification order, originally dated January 23, 2013, to update special controls organization and align special controls with existing design controls requirements.

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 with the following indications for use:

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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the FerriScan R2-MRI Analysis System, and substantially equivalent devices of this generic type, 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 Food, Drug and Cosmetic Act (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 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 device that has not been previously classified under the Act may 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 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. 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, for the previously stated indications for use, the FerriScan R2-MRI Analysis System 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. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
False positive result	Special controls (1), (2)(i), and (2)(ii)
False negative result	Special controls (1), (2)(i), and (2)(ii)
Sensitivity and specificity are not suitable for clinical decision making	Special controls (1) and (2)(iii)

In combination with 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) Design verification and validation must include nonclinical and clinical performance testing demonstrating the bias, precision, repeatability, and reproducibility of liver iron concentration measurements.
- (2) Labeling must include specifying:
 - (i) Instructions for acceptance testing of images prior to processing;
 - (ii) Data processing quality assurance protocols; and
 - (iii) The sensitivity and specificity of liver iron concentration measurements.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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 prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/comboination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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 request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you

may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Daniel Krainak at 301-796-0478.

Sincerely,

Robert Ochs, Ph.D.
Director
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health