Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 888.4515 to subpart E to read as follows:

§ 888.4515 Orthopedic manual surgical instrumentation for use with total disc replacement devices.

(a) *Identification.* Orthopedic manual surgical instrumentation for use with total disc replacement devices are non-powered hand-held devices designed specifically for use with a total disc replacement device and interface with the associated implant for the purpose of insertion, removal, placement, or repositioning, or to cut, rasp, or create a defect specific to the features of the associated implant. This type of device includes instruments specific to the geometry of the implant.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Technical specifications regarding geometry of the instruments must be specified and validated to demonstrate that the instruments can safely position, place, or remove the implant.

(2) The patient contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate that reprocessing of reusable devices that are provided non-sterile, or sterilization of devices provided sterile, is validated.

(4) Labeling must include:

(i) Identification of implant(s) and instruments which have been validated for use together; and

(ii) Validated methods and instructions for reprocessing any reusable parts.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16039 Filed 8–20–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2025–N–2369]

Medical Devices; Radiology Devices; Classification of the Liver Iron Concentration Imaging Companion Diagnostic for Deferasirox

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the liver iron concentration imaging companion diagnostic for deferasirox into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the liver iron concentration imaging companion diagnostic for deferasirox. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective August 21, 2025. The classification was applicable on January 23, 2013.

FOR FURTHER INFORMATION CONTACT: Daniel Krainak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3674, Silver Spring, MD 20993–0002, 301–796–0478, *Daniel.Krainak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the liver iron concentration imaging companion diagnostic for deferasirox as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo

classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 21, 2012, FDA received Resonance Health Services' request for De Novo classification of the FerriScan R2–MRI Analysis System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on January 23, 2013, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 892.1001.[1] We have named the generic type of device ''liver iron concentration imaging companion diagnostic for deferasirox'', and it is identified as 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.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—LIVER IRON CONCENTRATION IMAGING COMPANION DIAGNOSTIC FOR DEFERASIROX RISKS AND MITIGATION MEASURES

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).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

■ 1. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 892.1001 to subpart B to read as follows:

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

§ 892.1001 Liver iron concentration imaging companion diagnostic for deferasirox.

(a) *Identification.* 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.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16033 Filed 8–20–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 630

[Docket No. FHWA–2025–0019]

RIN 2125–AG26

Rescinding Regulations on Procedures for Advance Construction of Federal-Aid Projects

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FHWA rescinds a specific labeling provision of the rule issued on March 30, 1990, on Advance Construction of Federal-aid Projects.

DATES: This final rule is effective September 22, 2025.

FOR FURTHER INFORMATION CONTACT: For questions about this rulemaking, please contact Mr. Anthony DeSimone, FHWA Office of Infrastructure, 317–226–5307, or via email at *Anthony.DeSimone@dot.gov.* For legal questions, please contact Mr. Michael Harkins, FHWA Office of Chief Counsel, 202–366–1523, or via email at *Michael.Harkins@dot.gov.* Office hours for FHWA are from 8:00 a.m. to 4:30 p.m., eastern time (E.T.), Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, as well as the notice of proposed rulemaking (NPRM), and all comments received may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval assistance and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of Federal Register's website at *www.federalregister.gov* and the U.S. Government Publishing Office's website at *www.GovInfo.gov.*

I. General Discussion

FHWA is rescinding a specific provision of its rule on Advance Construction of Federal-Aid Projects, which was originally promulgated on December 8, 1983, at 48 FR 54972, and later amended on March 30, 1990, at 55 FR 11902. This provision is part of FHWA regulations, codified at 23 CFR part 630, subpart G, that prescribe procedures for advancing the construction of Federal-aid highway projects without obligating Federal funds apportioned or allocated to the State, known as Advance Construction (AC). 23 CFR 630.701. AC is authorized under 23 U.S.C. 115. Under the statute, FHWA [1] may authorize a State to proceed with a project authorized under Title 23 of the U.S. Code without the use of Federal funds while preserving eligibility for future Federal-aid funds. After an AC project is authorized, the State may convert the project to regular Federal-aid funding provided eligible Federal funds are made available for the project. For the reasons explained below, FHWA is rescinding a specific provision of those regulations, 23 CFR 630.705(b), as FHWA has determined it is unnecessary.

On December 8, 1983, FHWA issued a regulation revising FHWA's regulations concerning AC projects that existed at the time. Among the changes made, FHWA revised 23 CFR 630.703 to state: ''Project designations [for advance construction projects] shall be the same as for regular Federal-aid projects except that until the project is converted to a regular Federal-aid project, the prefix letters 'AC' for advance construction shall be used as the first letters of each project designation.'' *See* 48 FR at 54974. In issuing this provision, the preamble only stated that ''[p]rovisions for submitting programs and making project designations for advance construction projects now comprise § 630.703.'' On March 30, 1990, FHWA revised its AC regulations, moving the contents of what was previously 23 CFR 630.703 to 23 CFR 630.705, while only noting that regular AC procedures would then be contained in 23 CFR 630.705. *See* 55 FR at 11902. Through this 1990 rule, FHWA modified 23 CFR 630.705(b) to read: ''Project numbers shall be identified by the letters 'AC' preceding the regular project number prefix.'' *See* 55 FR at 11903. This provision, 23 CFR 630.705(b), has not been changed subsequently.

The requirements in 23 CFR 630.705(b) are not required by 23 U.S.C. 115. In addition, FHWA's current process of determining which projects are advance construction projects, versus Federal-aid projects where Federal-aid funds have already been obligated, does not require the use of the prefix ''AC.'' Accordingly, FHWA is eliminating this regulatory provision.

On May 30, 2025, at 90 FR 22872, FHWA published an NPRM proposing to rescind 23 CFR 630.705(b) and sought comment on all aspects of that proposal. The FHWA did not receive any public comments on its proposal and now adopts the proposal without change.

II. Rulemaking Analyses and Notices

A. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

This rule does not meet the criteria of a ''significant regulatory action'' under Executive Order (E.O.) 12866, as amended by E.O. 14215 and E.O. 13563. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those orders.

This rule rescinds regulations that are not in alignment with current FHWA process. For that reason, FHWA does not believe there are any costs to this rulemaking. FHWA anticipates some unquantified cost-savings associated

[1] Authority to administer 23 U.S.C. 115 is delegated to the FHWA under 49 CFR 1.85.