sequences, primer/probe design and rationale for target sequence selection.

(C) Computational path from collected raw data to reported result (*e.g.,* how collected raw signals are converted into a reported signal and result, as applicable.

(iii) A detailed documentation for device software, including, software applications and hardware-based devices that incorporate software.

Dated: June 9, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–10786 Filed 6–12–25; 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–1529]**

## Medical Devices; Radiology Devices; Classification of the Radiological Computer-Assisted Detection and Diagnosis Software

**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 radiological computer-assisted detection and diagnosis software 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 the radiological computer-assisted detection and diagnosis software's classification. We are taking this action because we have determined that classifying the device into class II (special controls) 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 June 13, 2025. The classification was applicable on May 24, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 301–796–2411, *Dina.Jerebitski@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

Upon request, FDA has classified radiological computer-assisted detection and diagnosis software 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 (see 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 February 5, 2018, FDA received Imagen Technologies, Inc.'s request for De Novo classification of the OsteoDetect. 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 May 24, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 892.2090.[1] We have named the generic type of device ''radiological computer-assisted detection and diagnosis software,'' and it is identified as an image processing device intended to aid in the detection, localization, and characterization of fracture, lesions, or other disease-specific findings on acquired medical images (*e.g.,* radiography, magnetic resonance, computed tomography). The device detects, identifies, and characterizes findings based on features or information extracted from images, and provides information about the presence, location, and characteristics of the findings to the user. The analysis is intended to inform the primary diagnostic and patient management decisions that are made by the clinical user. The device is not intended as a replacement for a complete clinician's review or their clinical judgment that takes into account other relevant information from the image or patient history.

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—RADIOLOGICAL COMPUTER-ASSISTED DETECTION AND DIAGNOSIS SOFTWARE RISKS AND MITIGATION MEASURES

| Identified risks to health | Mitigation measures |
|---|---|
| False positive results | General controls and special controls (1) (21 CFR 892.2090(b)(1)) and (2) (21 CFR 892.2090(b)(2)). |
| False negative results | General controls and special controls (1) (21 CFR 892.2090(b)(1)) and (2) (21 CFR 892.2090(b)(2)). |
| Device misuse (analyzing images from unintended patient population or of an unintended anatomical site; or images acquired with an unintended modality, incompatible imaging hardware, or incompatible image acquisition parameters) resulting in lower device performance (inappropriate detection/diagnosis information being displayed to the end user). | General controls and special controls (1) (21 CFR 892.2090(b)(1)) and (2) (21 CFR 892.2090(b)(2)). |
| Device failure leading to absence of results, delay of results, or incorrect results, leading to delayed or inaccurate patient diagnosis. | General controls and special controls (1) (21 CFR 892.2090(b)(1)) and (2) (21 CFR 892.2090(b)(2)). |

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, subpart 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 § 892.2090 to subpart B to read as follows:

### § 892.2090 Radiological computer-assisted detection and diagnosis software.

(a) *Identification.* A radiological computer-assisted detection and diagnostic software is an image processing device intended to aid in the detection, localization, and characterization of fracture, lesions, or other disease-specific findings on acquired medical images (*e.g.,* radiography, magnetic resonance, computed tomography). The device detects, identifies, and characterizes findings based on features or information extracted from images, and provides information about the presence, location, and characteristics of the findings to the user. The analysis is intended to inform the primary diagnostic and patient management decisions that are made by the clinical user. The device is not intended as a replacement for a complete clinician's review or their clinical judgment that takes into account other relevant information from the image or patient history.

[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.

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

(1) Design verification and validation must include:

(i) A detailed description of the image analysis algorithm, including a description of the algorithm inputs and outputs, each major component or block, how the algorithm and output affects or relates to clinical practice or patient care, and any algorithm limitations.

(ii) A detailed description of pre-specified performance testing protocols and dataset(s) used to assess whether the device will provide improved assisted-read detection and diagnostic performance as intended in the indicated user population(s), and to characterize the standalone device performance for labeling. Performance testing includes standalone test(s), side-by-side comparison(s), and/or a reader study, as applicable.

(iii) Results from standalone performance testing used to characterize the independent performance of the device separate from aided user performance. The performance assessment must be based on appropriate diagnostic accuracy measures (*e.g.,* receiver operator characteristic plot, sensitivity, specificity, positive and negative predictive values, and diagnostic likelihood ratio). Devices with localization output must include localization accuracy testing as a component of standalone testing. The test dataset must be representative of the typical patient population with enrichment made only to ensure that the test dataset contains a sufficient number of cases from important cohorts (*e.g.,* subsets defined by clinically relevant confounders, effect modifiers, concomitant disease, and subsets defined by image acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized for the intended use population and imaging equipment.

(iv) Results from performance testing that demonstrate that the device provides improved assisted-read detection and/or diagnostic performance as intended in the indicated user population(s) when used in accordance with the instructions for use. The reader population must be comprised of the intended user population in terms of clinical training, certification, and years of experience. The performance assessment must be based on appropriate diagnostic accuracy measures (*e.g.,* receiver operator characteristic plot, sensitivity, specificity, positive and negative predictive values, and diagnostic likelihood ratio). Test datasets must meet the requirements described in paragraph (b)(1)(iii) of this section.

(v) Appropriate software documentation, including device hazard analysis, software requirements specification document, software design specification document, traceability analysis, system level test protocol, pass/fail criteria, testing results, and cybersecurity measures.

(2) Labeling must include the following:

(i) A detailed description of the patient population for which the device is indicated for use.

(ii) A detailed description of the device instructions for use, including the intended reading protocol and how the user should interpret the device output.

(iii) A detailed description of the intended user, and any user training materials or programs that address appropriate reading protocols for the device, to ensure that the end user is fully aware of how to interpret and apply the device output.

(iv) A detailed description of the device inputs and outputs.

(v) A detailed description of compatible imaging hardware and imaging protocols.

(vi) Warnings, precautions, and limitations must include situations in which the device may fail or may not operate at its expected performance level (*e.g.,* poor image quality or for certain subpopulations), as applicable.

(vii) A detailed summary of the performance testing, including test methods, dataset characteristics, results, and a summary of sub-analyses on case distributions stratified by relevant confounders, such as anatomical characteristics, patient demographics and medical history, user experience, and imaging equipment.

Dated: June 9, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–10789 Filed 6–12–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 100

**[Docket Number USCG–2025–0257]**

**RIN 1625–AA08**

## Special Local Regulation; 4th of July Fireworks, Lower East River & Upper New York Bay, Manhattan and Brooklyn, NY

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a special local regulation on the navigable waters of the Lower East River and New York Harbor, NY, for a 4th of July fireworks display. This special local regulation allows the Coast Guard to control vessel movement and prohibit all vessel traffic from entering the fireworks barge buffer zone and establish four separate viewing areas. This rule is necessary to provide for the safety of life on the navigable waters immediately before, during, and after a fireworks display on a highly congested waterway.

**DATES:** This rule is effective from 5:30 p.m. on July 4 through 11:30 p.m. on July 5, 2025. It will only be subject to enforcement, however, during the hours of 5:30 p.m. to 11:30 p.m. on July 4, or, in the event the fireworks display is postponed due to inclement weather or other causes, from 5:30 p.m. to 11:30 p.m. on July 5, 2025.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2025–0257 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this rule, call or email Lieutenant Junior Grade Rebecca Fitzgerald-Smith, Waterways Management Division, U.S. Coast Guard; telephone 718–801–2932, email *Rebecca.R.Fitzgerald-Smith@uscg.mil.*

**SUPPLEMENTARY INFORMATION:**

### I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port New York
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
SLR Special Local Regulation
U.S.C. United States Code