sample collection device must be cleared in a premarket submission as a part of this device.

(2) The labeling required under § 809.10(b) of this chapter must include:

(i) An intended use that includes the following statements:

(A) A statement that the device detects and measures bacterial proteases from a swab saturated with wound fluid.

(B) A statement that the device provides a qualitative output to aid the user in assessing the risk for non-healing of wounds (*e.g.,* chronic venous, diabetic foot and pressure ulcers).

(C) A description of the clinical indications for test use.

(D) The specific population(s) for which the device is intended.

(E) A description of the recommended training (*e.g.,* knowledge and experience) for safe and effective use of the device and to minimize the risks of incorrect results and misinterpretation.

(ii) A detailed description of the performance characteristics of the device from the analytical and clinical studies required under paragraphs (b)(3)(ii) and (iii) of this section.

(iii) A detailed explanation of the interpretation of results.

(iv) A warning statement describing situations where the device has not been validated or may not perform as identified in the labeling (*e.g.,* not for use with wounds which are ≥6 months of age and ≥1 cm^2 in size).

(v) The following limiting statements:

(A) That the device is not intended to provide a risk assessment of chronic wound infection status or aid in the diagnosis of infection in chronic wounds, nor is the device intended for monitoring the effectiveness of anti-infective therapy.

(B) That a negative result does not exclude the presence of bacterial proteases. Therefore, the results should be used in conjunction with clinical findings to make an accurate assessment of risk of nonhealing. The test result should be interpreted in conjunction with other risk factors, along with clinical and laboratory data available to the clinician.

(C) That the device has been validated using wound fluid samples only. Other sample types (*e.g.,* whole blood from venous or capillary draws, other body fluids) have not been evaluated.

(D) That skin flora may secrete bacterial proteases therefore, swab contact with intact skin should be avoided as this may yield false positive results.

(vi) Labeling must include a brief reference sheet for healthcare professionals that includes the intended use, summary of clinical performance, results from analytical testing on normal skin and human proteases, and warning and limiting statements.

(3) Design verification and validation must include the following:

(i) A detailed device description (*e.g.,* all device parts, control elements incorporated into the test procedure, reagents required but not provided, and the principle of device operation and test methodology).

(ii) Detailed documentation and results from analytical studies, including the limit of detection, inclusivity, cross-reactivity, microbial interference, analytical sensitivity for normal skin flora and human proteases, interfering substances, specimen stability, within-lab precision, and reproducibility.

(iii) Detailed documentation and results from a clinical study that includes prospective (sequentially collected) samples for the intended specimen type that are representative of the intended use population(s). The clinical study must compare the device performance to results obtained from a reference or comparator method that FDA has determined is appropriate.

Dated: May 27, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09883 Filed 5–30–25; 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–1182]

Medical Devices; Radiology Devices; Classification of the Radiological Acquisition and/or Optimization Guidance System

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 acquisition and/or optimization guidance system 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 acquisition and/or optimization guidance system'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 2, 2025. The classification was applicable on February 7, 2020.

FOR FURTHER INFORMATION CONTACT: Shahram Vaezy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3656, Silver Spring, MD 20993–0002, 301–796–6242, *Shahram.Vaezy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the radiological acquisition and/or optimization guidance system 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 (see 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 August 27, 2019, FDA received Caption Health, Inc.'s request for De Novo classification of the Caption Guidance. 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 21 U.S.C. 360c(a)(1)(B)). 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 February 7, 2020, 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 892.2100.[1] We have named the generic type of device radiological acquisition and/or optimization guidance system, and it is identified as a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals. The device interfaces with the acquisition system, analyzes its output, and provides guidance and/or feedback to the operator for improving image and/or signal quality.

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 ACQUISITION AND/OR OPTIMIZATION GUIDANCE SYSTEM RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Device Error—Failure to provide guidance on acquiring diagnostic-quality images or signals, leading to delay, prolonged examination, or additional unnecessary procedures, due to: • Algorithm failure. • Hardware or software failure.	Design verification and validation, and Labeling.
User Error—Operator failure to follow the guidance provided by the device to acquire diagnostic-quality images or signals, leading to delay, prolonged examination, or additional unnecessary procedures, due to human error.	Design verification and validation, and Labeling.

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 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

[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.

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 parts 801 and 809, 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 § 892.2100 to subpart B to read as follows:

§ 892.2100 Radiological acquisition and/or optimization guidance system.

(a) *Identification.* A radiological acquisition and/or optimization guidance system is a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals. The device interfaces with the acquisition system, analyzes its output, and provides guidance and/or feedback to the operator for improving image and/or signal quality.

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

(1) Design verification and validation must include:

(i) A detailed, technical device description, including a detailed description of the impact of any software and hardware on the device's functions, the associated capabilities and limitations of each part, and the associated inputs and outputs.

(ii) A detailed, technical report on the non-clinical performance testing of the subject device in the intended use environments, using relevant consensus standards when applicable.

(iii) A detailed report on the clinical performance testing, obtained from either clinical testing, accepted virtual/physical systems designed to capture clinical variability, comparison to a closely-related device with established clinical performance, or other sources that are justified appropriately. The choice of the method must be justified given the risk of the device and the general acceptance of the test methods. The report must include the following:

(A) A thorough description of the testing protocol(s).

(B) A thorough, quantitative evaluation of the diagnostic utility and quality of images/data acquired, or optimized, using the device.

(C) A thorough, quantitative evaluation of the performance in a representative user population and patient population, under anticipated conditions and environments of use.

(D) A thorough discussion on the generalizability of the clinical performance testing results.

(E) A thorough discussion on use-related risk analysis/human factors data.

(iv) A detailed protocol that describes, in the event of a future change, the level of change in the device technical specifications or indications for use at which the change or changes could significantly affect the safety or effectiveness of the device and the risks posed by these changes. The assessment metrics, acceptance criteria, and analytical methods used for the performance testing of changes that are within the scope of the protocol must be included.

(v) Documentation of an appropriate training program, including instructions on how to acquire and process quality images and video clips, and a report on usability testing demonstrating the effectiveness of that training program on user performance, including acquiring and processing quality images.

(2) The labeling required under § 801.109(c) of this chapter must include:

(i) A detailed description of the device, including information on all required and/or compatible parts.

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

(iii) A detailed description of the intended user population, and the recommended user training.

(iv) Detailed instructions for use, including the information provided in the training program used to meet the requirements of paragraph (b)(1)(iv) of this section.

(v) A warning that the images and data acquired using the device are to be interpreted only by qualified medical professionals.

(vi) A detailed summary of the reports required under paragraphs (b)(1)(ii) and (iii) of this section.

(vii) A statement on upholding the As Low As Reasonably Achievable (ALARA) principle with a discussion on the associated device controls/options.

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09837 Filed 5–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2025–0435]

RIN 1625–AA00

Safety Zone; Gulf of America, Pass A Loutre State Wildlife Management Area

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone one nautical mile in all directions around well #59 at approximate position 29°04′28.919″ N, 089°10′48.720″ W, near the Pass A Loutre State Wildlife Management Area. The safety zone is needed to protect persons and critical infrastructure from the potential contamination due to an oil spill in the Gulf of America. Entry of vessels or persons into this zone, or movement of vessels within this zone is prohibited unless specifically authorized by the Captain of the Port or a designated representative.

DATES: This rule is effective without actual notice from June 2, 2025, through July 2, 2025. For the purposes of enforcement, actual notice will be used from May 22, 2025, until June 2, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2025–0435 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 Commander Xiaobin Tuo, Sector New Orleans, U.S. Coast Guard; 504–365–2246, email *Xiaobin.Tuo@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section