(v) Quality assurance protocols and detailed documentation for device software, including standalone software applications and hardware-based devices that incorporate software.

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

(i) A detailed explanation of the interpretation of results and acceptance criteria.

(ii) A limiting statement indicating that negative results do not preclude HSV–1 or HSV–2 infection and should not be used as the sole basis for treatment or other patient management decisions.

Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11794 Filed 6–25–25; 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–1361]

Medical Devices; Radiology Devices; Classification of the Cream for X-Ray Attenuation

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 cream for x-ray attenuation 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 cream for x-ray attenuation'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 26, 2025. The classification was applicable on May 9, 2013.

FOR FURTHER INFORMATION CONTACT: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3572, Silver Spring, MD 20993–0002, 301–796–6217, *Scott.Mcfarland@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the cream for x-ray attenuation 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 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 4, 2013, FDA received BloXR Corporation's request for De Novo classification of the X-ray Attenuating Cream. 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 general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 9, 2013, FDA issued an order to the requestor classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 892.6510.[1] We have named the generic type of device cream for x-ray attenuation, and it is a sterile cream intended for use as a radiation shield. It is intended to be applied to the user's hand before donning gloves, or it may be applied on a glove on the hand, followed by donning a second glove. Cream for x-ray attenuation is intended to be used during medical procedures in which hands are necessarily exposed to radiation to offer some degree of protection from radiation exposure in the diagnostic imaging range of up to 130 kVp. This may include surgical procedures that require the use of fluoroscopy or radiography or other procedures. Cream for x-ray attenuation is not intended to be used in or adjacent to the primary x-ray beam or the transmitted beam and should not be used in lieu of a Radiographic Procedure Glove, which is used in radiography for those studies requiring the physician's hand or forearm be in the direct path of the primary x-ray beam.

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—CREAM FOR X-RAY ATTENUATION RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction to health care professionals and patients as a result of direct contact to the skin.	(1) Biocompatibility testing, (2) Surgical glove compatibility performance testing, and (3) Identification of compatible surgical gloves in labeling.
Infection risk to patient as a result of patient contact with contaminated cream due to glove failure and the cream flaking off onto the patient.	(1) Sterilization, packaging, and expiration date testing, (2) Sterile device and expiration date statement in labeling, (3) Surgical glove compatibility performance testing, and (4) Identification of compatible surgical gloves in labeling.
Radiation exposure to health care professionals due to lack of radiation attenuation because of cream formulation. The radiation attenuating agent in the cream may not be present in high enough concentration or is not appropriate to provide the amount of protection needed.	(1) Boxed warning in labeling, (2) Attenuation information in labeling, (3) Surgical glove compatibility performance testing, (4) Attenuation performance testing, and (5) Application performance testing.
Radiation exposure to health care professional during actual use (lack of effectiveness). Lack of continuous protection during actual use can result from poor cream composition such that the cream will absorb, crack, flake off, etc. during use in a clinical setting.	(1) Boxed warning in labeling, (2) Attenuation information in labeling, (3) Surgical glove compatibility performance testing, (4) Attenuation performance testing, (5) Application performance testing, and (6) Validated device application instructions for effective shielding in labeling.
Radiation exposure to health care professionals due to inconsistent device application. Radiation exposure can result due to inadequate instructions describing how to apply the cream to ensure that the hands are completely covered and covered with enough cream to provide the amount of radiation protection stated in the labeling.	(1) Validated device application instructions for effective shielding in labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the 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. 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, and 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:

[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.

PART 892—RADIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 892 continues to read as follows:

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

■ 2. Add § 892.6510 to subpart G to read as follows:

§ 892.6510 Cream for x-ray attenuation.

(a) *Identification.* A cream for x-ray attenuation is a sterile cream intended for use as a radiation shield. It is intended to be applied to the user's hand before donning gloves, or it may be applied on a glove on the hand, followed by donning a second glove. Cream for x-ray attenuation is intended to be used during medical procedures in which hands are necessarily exposed to radiation to offer some degree of protection from radiation exposure in the diagnostic imaging range of up to 130 kVp. This may include surgical procedures that require the use of fluoroscopy or radiography or other procedures. Cream for x-ray attenuation is not intended to be used in or adjacent to the primary x-ray beam or the transmitted beam and should not be used in lieu of a Radiographic Procedure Glove, which is used in radiography for those studies requiring the physician's hand or forearm be in the direct path of the primary x-ray beam.

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

(1) Design verification and validation must include documentation of results from safety and effectiveness testing. The results from safety and effectiveness testing must include:

(i) Biocompatibility data consistent with the intended use for the device;

(ii) Sterilization, packaging, and expiration date testing; and

(iii) Nonclinical and/or clinical performance testing representative of ''as use'' conditions demonstrating:

(A) Compatibility to the type(s) of surgical glove (*e.g.,* latex, nitrile, vinyl) to be used with the device;

(B) Attenuation performance; and

(C) Proper application of the device.

(2) Labeling must include:

(i) A statement that the device is sterile and an expiration date.

(ii) A boxed warning statement prominently placed in all labeling material for these devices. That boxed warning statement must read: ''The device is not intended to be used in or adjacent to the primary X-ray beam or transmitted beam and should not be used in lieu of a Radiographic Procedure Glove, which is used in radiography for those studies requiring the physician's hand or forearm be in the direct path of the primary X-ray beam.''

(iii) The methods and results from nonclinical and/or clinical performance testing representative of ''as use'' conditions demonstrating the amount of attenuation the device provides to the end user at 60, 80, 100, and 120 kVp.

(iv) Validated instructions for use for device application and a statement of how often the device must be removed and reapplied for effective shielding.

(v) Identification of the type(s) of surgical glove (*e.g.,* latex, nitrile, vinyl) that is compatible for use with the device.

Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11791 Filed 6–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2025–0428]

RIN 1625–AA08

Special Local Regulation; Marine Events; Annual Bayview Mackinac Race, Lake Huron, MI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the annual Bayview Yacht Club Port Huron to Mackinac Race. This action is necessary to safely control vessel movements in the vicinity of the race and provide for the safety of the general boating public and commercial shipping. During this enforcement period, no person or vessel may enter the regulated area without the permission of the Coast Guard Patrol Commander (PATCOM).

DATES: The regulation in 33 CFR 100.902 will be enforced from 10 a.m. through 3 p.m. on July 12, 2025.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Tracy Girard, Waterway Management Division, U.S. Coast Guard Sector Detroit, 110 Mt. Elliott Street, Detroit, MI at (313) 568–9564 or *Tracy.M.Girard@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.902 for the Annual Bayview Mackinac Race from 10 a.m. through 3 p.m. on July 12, 2025. This action is being taken to provide for the safe control vessel movements in the vicinity of the race and provide for the safety of the general boating public and commercial shipping. Our regulation for marine events within the Captain of the Port Detroit zone in § 100.902(a) specifies the location of the regulated area for the Annual Bayview Mackinac Race. During the enforcement period, no vessel may enter the regulated area without prior approval from the Coast Guard's designated Patrol Commander (PATCOM). The PATCOM may restrict vessel operation within the regulated area to vessels having particular operating characteristics. Vessels desiring to transit the regulated area may do so only with prior approval of the PATCOM and when so directed by that officer. The PATCOM may be contacted on Channel 16 (156.8 MHZ) by the call sign ''Coast Guard Patrol Commander.'' Vessels permitted to transit the regulated area will operate at no wake speed and in a manner which will not endanger participants in the event or any other craft.

If the District Commander, Captain of the Port, or PATCOM determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: June 11, 2025.

Richard P. Armstrong,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2025–11802 Filed 6–25–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0270]

RIN 1625–AA00

Safety Zone; Milwaukee Air and Water Show, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending a published safety zone for certain waters of Lake Michigan encompassing the Milwaukee Air and Water Show to include an additional day. This action is necessary to provide for the safety of life on these navigable waters in the vicinity