(J) Any observed adverse events and complications.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2026–N–4270]

Medical Devices; Radiology Devices; Classification of the Radiation Therapy Marking Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the radiation therapy marking device 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 radiation therapy marking device. 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 April 30, 2026. The classification was applicable on December 10, 2021.

FOR FURTHER INFORMATION CONTACT: Lynne Fairobent, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3663, Silver Spring, MD 20993–0002, 301–796–4817, *Lynne.Fairobent@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the radiation therapy marking device into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness of the device. 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 into, 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 classification 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 premarket notification (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 June 22, 2020, FDA received Medical Precision B.V.'s request for De Novo classification of the Comfort Marker 2.0. 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 of the device, 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 December 10, 2021, 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 892.5785.[1] We have named the

[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

generic type of device ''radiation therapy marking device,'' and it is identified as a powered device that transdermally delivers a permanent or temporary colorant to the skin for the purpose of placing marks to guide radiation therapy. This classification does not include devices with reusable or reprocessed needles or devices intended for diagnostic, therapeutic, or aesthetic use or to deliver other products for these uses.

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

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR THE RADIATION THERAPY MARKING DEVICE

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Cross contamination and infection	Reprocessing validation; Sterilization validation; Non-clinical performance testing; Shelf-life testing; and Labeling.
Needle stick injury to provider	Non-clinical performance testing; and Labeling.
Device and/or software failure leading to ineffective marking	Clinical performance testing; Non-clinical performance testing; Software validation, verification, and hazard analysis; and Labeling.
Electrical shock or electromagnetic interference with other devices.	Electromagnetic compatibility testing; Electrical safety testing; 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 of the device. 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.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for radiation therapy marking devices. This device is therefore 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 normally 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 management 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 § 892.5785 to subpart F to read as follows:

§ 892.5785 Radiation therapy marking device.

(a) *Identification.* A radiation therapy marking device is a powered device that transdermally delivers a permanent or temporary colorant to the skin for the purpose of placing marks to guide radiation therapy. This classification does not include devices with reusable or reprocessed needles or devices intended for diagnostic, therapeutic, or aesthetic use or to deliver other products for these uses.

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

(1) Design verification and validation must include:

(i) Documentation of performance data from studies that demonstrate:

(A) The indicated colorant is compatible with the device and its method of delivery;

(B) The device can reproducibly deliver the indicated colorant with the specifications described; and

(C) The length of time that compatible colorants remain visible on the skin following device application.

(ii) Documentation of performance data from studies that demonstrate:

(A) Accuracy and reproducibility of needle penetration depth;

(B) Device protection from cross-contamination, including fluid ingress protection;

(C) Adequacy of the cleaning and disinfection instructions to ensure that the reusable components of the device can be cleaned and disinfected; and

(D) The sterility of all patient-contacting components (*e.g.,* safety needle).

(iii) Documentation of performance data from studies that demonstrate electrical safety and electromagnetic compatibility of all electrical components of the device.

(iv) Documentation of performance data from studies that demonstrate continued sterility, package integrity,

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.

and device functionality over the intended shelf life.

(v) Documentation of software verification, validation, and hazard analysis.

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

(i) An explanation of the device and the mechanism of operation;

(ii) Validated methods and instructions for reprocessing of any reusable components;

(iii) Disposal instructions; and

(iv) A shelf life for all sterile components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–08424 Filed 4–29–26; 8:45 am]

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DEPARTMENT OF JUSTICE

28 CFR Part 68

[Docket No. 19–0312; Dir. Order No. 05–2026]

RIN 1125–AB06

Office of the Chief Administrative Hearing Officer, Chief Administrative Law Judge

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: Final rule.

SUMMARY: On October 7, 2020, the Department of Justice (''Department'') published an interim final rule (''IFR'') amending the regulations governing the Office of the Chief Administrative Hearing Officer (''OCAHO''). The amendments reflected changes related to the creation of the position of the Chief Administrative Law Judge (''CALJ'') and made additional related technical changes. This final rule adopts the provisions of the IFR with minor technical corrections.

DATES: This rule is effective April 30, 2026.

FOR FURTHER INFORMATION CONTACT: Jamee E. Comans, Acting Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500 Falls Church, VA 22041, telephone (703) 305–0289.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

The Department is issuing this final rule pursuant to section 103(g) of the Immigration and Nationality Act (''INA'' or ''Act''), 8 U.S.C. 1103(g), as amended by the Homeland Security Act of 2002 (''HSA''), Public Law 107–296, 116 Stat. 2135 (as amended). Under the HSA, the Attorney General retains the authority to ''establish such regulations, . . . issue such instructions, review such administrative determinations in immigration proceedings, delegate such authority, and perform such other acts as the Attorney General determines to be necessary for carrying out'' the Attorney General's authorities under the INA. HSA 1102, 116 Stat. at 2274 (codified at 8 U.S.C. 1103(g)(2)). In Attorney General Order Number 6260–2025, pursuant to 28 U.S.C. 509 and 510, the Attorney General has delegated authority to issue regulations related to immigration matters within the jurisdiction of the Executive Office of Immigration Review (''EOIR'') to EOIR's Director.

II. Summary of the IFR

On October 7, 2020, the Department published an IFR amending the regulations governing OCAHO. Office of the Chief Administrative Hearing Officer, Chief Administrative Law Judge, 85 FR 63204 (Oct. 7, 2020).

The IFR revised §§ 68.2, 68.3, 68.8, 68.15, 68.26, 68.29, 68.30, 68.33, 68.55, and 68.57 in title 28 of the Code of Federal Regulations (''CFR'').[1]

A. Chief Administrative Law Judge

The IFR amended part 68 of chapter I of title 28 of the CFR to reflect the creation of a CALJ position within OCAHO and to delineate the responsibilities and authorities of the CALJ and the Chief Administrative Hearing Officer (''CAHO''). *See* 85 FR 63205. Specifically, the IFR provided that the CALJ will serve as an Administrative Law Judge (''ALJ'') while also serving as the direct supervisor of the other OCAHO ALJs and ALJ support staff. *Id.* The CAHO, in turn, will supervise the CALJ and the non-ALJ support staff. *Id.* In addition, in order to avoid recusal issues resulting from OCAHO's increasing size, the IFR directed that (1) if an ALJ is disqualified from adjudicating a case, the CALJ will reassign the case to another ALJ; (2) if the CALJ is disqualified from adjudicating a case, the CAHO will reassign the case to another ALJ; (3) if the CAHO is disqualified from reviewing an interlocutory order under 28 CFR 68.53 or a final order under 28 CFR 68.54, the review will be reassigned to the EOIR Director; and (4) the disqualification procedures for ALJs in 28 CFR 68.30 also apply to the CAHO conducting an administrative review under 28 CFR 68.53 or 68.54. *See* 28 CFR 68.30.

B. Technical Changes

The IFR also made a variety of related technical edits to 28 CFR part 68.

First, the IFR amended various references to the ''Chief Administrative Hearing Officer'' to read ''Chief Administrative Law Judge'' in 28 CFR part 68 to reflect the division of responsibility described above. *See, e.g.,* 28 CFR 68.26, 68.29.

Second, the IFR made technical changes at 28 CFR 68.15, 68.33, 68.55, and 68.57 that replaced outdated references to the former Immigration and Naturalization Service (''INS'') with references that reflect the current agency organization in the Department of Homeland Security (''DHS''). *See* HSA, Pub. L. 107–296, 116 Stat. 2135, as amended.

Third, the IFR italicized defined terms in 28 CFR 68.2 to improve clarity, made stylistic changes in 28 CFR 68.2, and amended a typographical error in the cross-reference at 28 CFR 68.33(c)(3)(iv).[2]

III. Public Comments on the IFR

The Department received no comments from the public on the IFR.[3]

IV. Provisions of the Final Rule

After receiving no public comments, the Department adopts the provisions of the IFR as final with minor technical corrections set forth in this section of the preamble.

First, the final rule further amends the definition of ''pleading'' in 28 CFR 68.2. The IFR defined ''pleading'' to include the following documents submitted to the ALJ or, when no judge is assigned, the CALJ: the complaint, the answer, any motions (including any supplements or amendments to the motions or amendments), and any permitted replies to any of the aforementioned documents. 28 CFR 68.2. Upon further consideration, the Department believes that the IFR's definition could be interpreted as inconsistent with other provisions of 28 CFR part 68.

Certain provisions of 28 CFR part 68 require specific pleadings to be filed with the CAHO rather than with an ALJ or CALJ, as set forth in the IFR's

[1] The preamble to the IFR incorrectly stated that it included an amendment to 28 CFR 68.23. *See* 85 FR 63205.

[2] The preamble to the IFR incorrectly stated that the section including the updated cross-reference was at 28 CFR 68.33(d)(iv). *See* 85 FR 63205.

[3] The record reflects one comment received, but this comment is a test comment submitted by the Department itself and not a comment from the public.