(h) Exceptions to EASA AD 2025–0096

(1) Where paragraphs (1) and (6.2) of EASA AD 2025–0096 refer to its effective date, this AD requires August 29, 2025 (the effective date of AD 2025–16–12).

(2) Where paragraph (4) of EASA AD 2025–0096 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraphs (1) and (3) of EASA AD 2025–0096 specify to ''inform all flight crews, and, thereafter, operate the aeroplane accordingly,'' this AD does not require those actions as those actions are already required by existing FAA operating regulations (see 14 CFR 91.9, 91.505, 121.137, and 121.628(a)(2) and (a)(5)).

(4) Where paragraph (3) of EASA AD 2025–0096 specifies to ''implement the instructions of the MMEL update, as applicable, depending on aeroplane configuration (see Note 1 of this AD), on the basis of which the operator's MEL must be amended'', this AD requires replacing that text with ''revise the operator's existing FAA-approved MEL by incorporating the applicable information identified in ''The MMEL update'' as defined in EASA AD 2025–0096''.

(5) Where the service information required by EASA AD 2025–0096 specifies discarding parts, this AD requires removing those parts from service.

(6) This AD does not adopt the ''Remarks'' section of EASA AD 2025–0096.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* the Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD and email to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any material contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Additional Information

(1) For more information about this AD, contact Frank Carreras, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3539; email: *Frank.Carreras@faa.gov.*

(2) For Airbus material identified in this AD that is not incorporated by reference, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* website *airbus.com.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following material was approved for IBR on August 29, 2025 (90 FR 39102, August 14, 2025; corrected August 22, 2025 (90 FR 40964)).

(i) European Union Aviation Safety Agency (EASA) AD 2025–0096, dated April 28, 2025.

(ii) [Reserved]

(4) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

(5) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(6) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on July 23, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–15308 Filed 7–28–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2026–N–7955]

Medical Devices; Radiology Devices; Classification of the Phase-Changing Fiducial Marker for Radiation Therapy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the phase-changing fiducial marker for radiation therapy 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 phase-changing fiducial marker for radiation therapy. 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 July 29, 2026. The classification was applicable on December 23, 2022.

FOR FURTHER INFORMATION CONTACT: Lora Weidner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3652, Silver Spring, MD 20993–0002, 240–402–6424, *Lora.Weidner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the phase-changing fiducial marker for radiation therapy 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

For this device, FDA issued an order on August 13, 2015, finding the BioXmark not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On March 4, 2022, FDA received Nanovi A/S's request for De Novo classification of the BioXmark device. 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 23, 2022, 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 892.5727.[1] We have named the generic type of device ''phase-changing fiducial marker for radiation therapy,'' and it is identified as a single-use, sterile liquid material that changes phase in situ when injected in tissue for the purposes of aiding radiation therapy treatment. The device is intended to be visualized using one or more radiologic imaging modalities.

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 PHASE-CHANGING FIDUCIAL MARKERS FOR RADIATION THERAPY

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation; and Animal performance testing.
Interference with image-guided radiation therapy or radiotherapy response assessment.	Clinical performance testing; Non-clinical performance testing; and Labeling.
Treatment delays due to device malfunction, marker migration, or inability to locate marker on imaging.	Clinical performance testing; Non-clinical performance testing; and Labeling.
Infection	Sterilization validation; Shelf life testing; and Labeling.
Inaccurate radiation dose delivery due to incorrect marker positioning, marker migration, or implantation.	Clinical performance testing; Non-clinical performance testing; Usability testing; and Labeling.
Complications due to implantation of marker or marker migration	Clinical performance testing; Animal performance testing; and Labeling.

[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.

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. FDA supports the principles of the ''3Rs,'' to replace, reduce, and/or refine animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

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 phase-changing fiducial markers for radiation therapy. 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 § 892.5727 to subpart F to read as follows:

§ 892.5727 Phase-changing fiducial marker for radiation therapy.

(a) *Identification.* A phase-changing fiducial marker for radiation therapy is a single-use, sterile liquid material that changes phase in situ when injected in tissue for the purposes of aiding radiation therapy treatment. The device is intended to be visualized using one or more radiologic imaging modalities.

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

(1) Clinical performance data under anticipated conditions of use must evaluate:

(i) Risk of marker migration in tissue during the course of radiation therapy through post-treatment follow-up;

(ii) The ability to visualize the marker to allow for adequate localization during the course of radiation therapy through post-treatment follow-up;

(iii) Risk of device interference with tumor response assessment post-treatment; and

(iv) All adverse events.

(2) Animal performance data under anticipated conditions of use must evaluate device toxicity and the risk of marker migration.

(3) Non-clinical performance data under anticipated conditions of use must evaluate:

(i) Maintenance of physical form throughout the course of therapy and post-treatment follow-up;

(ii) Device visibility on one or more radiologic imaging modalities; and

(iii) Device interference with radiation dose delivery.

(4) Performance testing must demonstrate the patient-contacting components of the device are biocompatible.

(5) Performance testing must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(6) Performance testing must demonstrate device sterility and non-pyrogenicity.

(7) Usability testing must demonstrate that the device can be positioned as indicated based solely on reading the directions for use.

(8) The labeling must include:

(i) A detailed description of the device including materials and composition, chemical and physical properties, a description of the mechanism of the change of phase, and timeframe for achieving final state;

(ii) Summary of all reported device-related adverse events from clinical testing;

(iii) Information describing the injection procedure, including any use of image guidance, and the range of compatible injection needle gauges; and

(iv) A shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15303 Filed 7–28–26; 8:45 am]

BILLING CODE 4164–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

Correction

In rule document 2026–13124, appearing on pages 39463–39465 in the issue of Tuesday, June 30, 2026, make the following corrections:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

§ 4044.54 [Corrected].

■ 1. On page 39464, the table, the heading titled ''TABLE 1 TO PARAGRAPH—SPREADS'' should read ''TABLE 1 TO PARAGRAPH(e)—SPREADS''

■ 2. On page 39465, in the table, the heading titled ''TABLE 1 TO PARAGRAPH—SPREADS—Continued'' should read ''TABLE 1 TO