

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 892**

[Docket No. FDA-2017-N-6855]

Medical Devices; Radiology Devices; Classification of the Rectal Balloon for Prostate Immobilization**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the rectal balloon for prostate immobilization 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 rectal balloon for prostate immobilization'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 December 27, 2017. The classification was applicable on January 28, 2014.

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SUPPLEMENTARY INFORMATION:**I. Background**

Upon request, FDA has classified the rectal balloon for prostate immobilization 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 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. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). 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. As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On July 15, 2013, RadiaDyne, LLC submitted a request for De Novo classification of the prostate immobilizer rectal balloon. 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 January 28, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 892.5720. We have named the generic type of device rectal balloon for prostate immobilization, and it is identified as a single use, inflatable, non-powered positioning device placed in the rectum to immobilize the prostate in patients undergoing radiation therapy. The device is intended to be used during all the phases of radiation therapy, including treatment planning, image verification, and radiotherapy delivery.

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—RECTAL BALLOON FOR PROSTATE IMMOBILIZATION RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures/21 CFR section
Anorectal Toxicity	Special controls (1)(i) (21 CFR 892.5720(b)(1)(i)), (1)(ii) (21 CFR 892.5720(b)(1)(ii)), (1)(iii) (21 CFR 892.5720(b)(1)(iii)), (1)(iv) (21 CFR 892.5720(b)(1)(iv)), (2)(i)(D) (21 CFR 892.5720(b)(2)(i)(D)), (2)(ii) (21 CFR 892.5720(b)(2)(ii)), (2)(iii) (21 CFR 892.5720(b)(2)(iii)), and (2)(iv) (21 CFR 892.5720(b)(2)(iv)).
Tissue Damage	Special controls (1)(iv) (21 CFR 892.5720(b)(1)(iv)), (1)(v) (21 CFR 892.5720(b)(1)(v)), (2)(i)(A) (21 CFR 892.5720(b)(2)(i)(A)), (2)(i)(D) (21 CFR 892.5720(b)(2)(i)(D)), (2)(ii) (21 CFR 892.5720(b)(2)(ii)), (2)(iii) (21 CFR 892.5720(b)(2)(iii)), and (2)(iv) (21 CFR 892.5720(b)(2)(iv)).
Perforation of the Rectum	Special controls (1)(v)(A) (21 CFR 892.5720(b)(1)(v)(A)), (1)(v)(B) (21 CFR 892.5720(b)(1)(v)(B)), (2)(i)(A) (21 CFR 892.5720(b)(2)(i)(A)), (2)(i)(D) (21 CFR 892.5720(b)(2)(i)(D)), (2)(ii) (21 CFR 892.5720(b)(2)(ii)), (2)(iii) (21 CFR 892.5720(b)(2)(iii)), and (2)(iv) (21 CFR 892.5720(b)(2)(iv)).
Irradiation of Healthy Tissue	Special controls (1)(v)(A) (21 CFR 892.5720(b)(1)(v)(A)), (1)(v)(B) (21 CFR 892.5720(b)(1)(v)(B)), (2)(i)(B) (21 CFR 892.5720(b)(2)(i)(B)), (2)(ii) (21 CFR 892.5720(b)(2)(ii)), (2)(iii) (21 CFR 892.5720(b)(2)(iii)), and (2)(iv) (21 CFR 892.5720(b)(2)(iv)).
Patient Intolerance	Special controls (1)(v)(A) (21 CFR 892.5720(b)(1)(v)(A)), (2)(i)(A) (21 CFR 892.5720(b)(2)(i)(A)), (2)(i)(C) (21 CFR 892.5720(b)(2)(i)(C)), (2)(ii) (21 CFR 892.5720(b)(2)(ii)), (2)(iii) (21 CFR 892.5720(b)(2)(iii)), and (2)(iv) (21 CFR 892.5720(b)(2)(iv)).

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).

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. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” 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; 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 is revised to read as follows:

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

- 2. Add § 892.5720 to subpart F to read as follows:

§ 892.5720 Rectal balloon for prostate immobilization.

(a) *Identification.* A rectal balloon for prostate immobilization is a single use, inflatable, non-powered positioning device placed in the rectum to immobilize the prostate in patients undergoing radiation therapy. The device is intended to be used during all the phases of radiation therapy, including treatment planning, image verification, and radiotherapy delivery.

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

(1) The premarket notification submission must include methodology and results of the following non-clinical and clinical performance testing:

- (i) Biocompatibility testing of the final finished device;
- (ii) If provided sterile, sterilization validation;

(iii) If not provided sterile, bioburden testing of the final finished device;

(iv) Shelf life and expiration date validation; and

(v) Performance testing including but not limited to:

(A) Venting mechanism (if device has a vent mechanism);

(B) Safety mechanism(s) to prevent advancement beyond its intended safe placement; and

(C) Structural integrity testing (e.g., tensile strength, balloon leakage and burst strength).

(2) Labeling that includes:

(i) Appropriate warnings and contraindications, including, but not limited to the following statements:

(A) “Do not transport the patient with the rectal balloon inserted. The balloon should be removed prior to transport.”;

(B) “Failure to perform the standard imaging position verification protocol may cause the device to not perform as intended.”;

(C) “Reduce the rectal balloon fill volume if the patient experiences discomfort due to the rectal balloon inflation.”; and

(D) “Do not apply excessive pressure/force on the shaft or tubing of the rectal balloon.”

(ii) Adequate instructions for use on the proper insertion procedure, positioning, and inflation of the rectal balloon;

(iii) Whether the device is sterile or non-sterile; and

(iv) An expiration date.

Dated: December 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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