(*e.g.,* soiling, room objects and surfaces, distances);

(iii) In-use testing must evaluate device performance under real-world use conditions;

(iv) Performance testing must demonstrate the photobiological safety of any lamps or lamp systems;

(v) Performance testing must evaluate safety features intended to prevent exposure and ensure that device operation can only occur in an unoccupied environment; and

(vi) Performance testing must characterize the long-term material compatibility of the microbiocidal agent on clinically relevant surfaces and/or devices.

(2) Biocompatibility testing must demonstrate safe residual levels of chemicals on medical devices surfaces and/or gaseous byproducts in air.

(3) Software verification, validation, and hazard analysis must be performed for any software components.

(4) Performance data must demonstrate the electromagnetic compatibility and electrical safety of the device.

(5) Labeling must include:

(i) Warnings and instructions to ensure the device is operated in an unoccupied environment;

(ii) Setup and positioning instructions; and

(iii) Information regarding material compatibility.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18426 Filed 9–9–26; 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–2026–N–9904]

Medical Devices; Radiology Devices; Classification of the Vaginal Hydrogel Packing System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the vaginal hydrogel packing 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 classification of the vaginal hydrogel packing system. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 September 10, 2026. The classification was applicable on August 22, 2023.

FOR FURTHER INFORMATION CONTACT: Justina Tam, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3661, Silver Spring, MD 20993–0002, 240–402–4974, *Justina.Tam@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the vaginal hydrogel packing system into class II (special controls), which we have determined will provide a reasonable assurance of the 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 August 26, 2022, FDA received BrachyFoam, Inc. (d/b/a Advaray)'s request for De Novo classification of the BrachyGel Vaginal Hydrogel Packing

System. 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 the 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 August 22, 2023, 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 892.5735.[1] We have named the generic type of device ''vaginal hydrogel packing system,'' and it is identified as a non-powered positioning device composed of a flexible container filled with a hydrogel. The device is intended to reduce the radiation dose delivered to adjacent pelvic organs by temporarily displacing the vaginal wall and adjacent pelvic tissues during radiation therapy treatment planning and delivery.

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 VAGINAL HYDROGEL PACKING SYSTEMS

Identified risks to health	Mitigation measures
Unintended irradiation of healthy tissue and/or underdosing of the target.	Clinical performance data; Performance testing; and Labeling.
Tissue damage from device instability, failure, or removal	Clinical performance data; Non-clinical performance testing; and Labeling.
Infection	Sterilization validation; Non-clinical performance testing; Labeling; and Shelf-life testing.
Adverse tissue reaction	Biocompatibility evaluation.
Prolonged or delayed procedure due to delays caused by device deployment, instability, or failure.	Clinical performance data; and Labeling.
Patient discomfort	Clinical performance data; and 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 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 vaginal hydrogel packing systems. 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 § 892.5735 to subpart F to read as follows:

§ 892.5735 Vaginal hydrogel packing system.

(a) *Identification.* A vaginal hydrogel packing system is a non-powered positioning device composed of a flexible container filled with a hydrogel. The device is intended to reduce the radiation dose delivered to adjacent pelvic organs by temporarily displacing the vaginal wall and adjacent pelvic tissues during radiation therapy treatment planning and delivery.

[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.

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

(1) Clinical performance data must demonstrate the device performs as intended under anticipated conditions of use and evaluate the following:

(i) Radiation dose to adjacent organs at risk;

(ii) Device stability;

(iii) Ability to deploy, expand, and remove the device; and

(iv) Patient comfort.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:

(i) Testing to evaluate the effect of therapeutic radiation levels on device integrity;

(ii) Bioburden testing to demonstrate the device does not pose an infection risk, if the device is not provided sterile; and

(iii) Structural integrity testing of the container, including tensile strength, container leakage, and burst strength.

(3) Performance testing must demonstrate space creation and maintenance for the duration of a radiation treatment fraction.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance data must demonstrate the sterility of patient-contacting components of the device that are provided sterile.

(6) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the labeled shelf life.

(7) Labeling must include:

(i) Warnings that:

(A) A three-dimensional imaging method is needed to ensure the device is placed correctly; and

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

(ii) Instructions on how to proceed if the device fails to perform as intended;

(iii) A summary of clinical data relevant to the device, including device-related complications; and

(iv) An expiration date or shelf life.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18427 Filed 9–9–26; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Iranian Transactions and Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; stay of effectiveness.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is indefinitely suspending three general licenses and one licensing policy issued pursuant to the Iranian Transactions and Sanctions Regulations to align with changes in the foreign policy of the United States towards Iran.

DATES: Effective September 8, 2026, 31 CFR 560.522, 560.528, and 560.529 are stayed indefinitely.

As of September 8, 2026, the effectiveness of Iran General License J–1, which is available on OFAC's website (*https://ofac.treasury.gov*), is stayed indefinitely.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Regulatory Affairs, 202–622–4855; or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Background

On October 22, 2012, OFAC issued a final rule that amended the former Iranian Transactions Regulations, 31 CFR part 560 (ITR), and reissued them in their entirety as the Iranian Transactions and Sanctions Regulations (ITSR or ''the Regulations'') (77 FR 64664, October 22, 2012). Since then, OFAC has amended the Regulations on several occasions.

On December 15, 2016, OFAC published on its website General License J–1, which was issued pursuant to the Regulations. This general license is available on OFAC's website (*www.treasury.gov/ofac*).

Rules To Be Stayed

In response to Iran's continued disruptions to global energy markets, attacks on partners and allies in the Middle East, reconstitution of its conventional and nuclear weapons programs, efforts to monetize the Strait of Hormuz, and continued support to terrorist proxies, OFAC is indefinitely suspending the general licenses and licensing policy contained at 31 CFR 560.522, 560.528, and 560.529. These general licenses and licensing policy authorize, respectively, certain payments for overflights of Iranian airspace; the issuance of specific licenses for certain transactions related to aircraft safety; and bunkering and emergency repairs. As a result of this suspension, any such transactions are no longer authorized by OFAC as of September 8, 2026.

In addition, OFAC is suspending indefinitely Iran General License J–1, published on OFAC's website on December 15, 2016. Iran General License J–1 authorizes the reexportation of certain civil aircraft to Iran on temporary sojourn, as well as related transactions. As a result of this suspension, any such transactions are no longer authorized by OFAC as of September 8, 2026.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of E.O. 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), as amended, and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, as well as the provisions of E.O. 14192 of January 31, 2025, ''Unleashing Prosperity Through Deregulation'' (90 FR 9065, February 6, 2025) and E.O. 14219 of February 19, 2025, ''Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative'' (90 FR 10583, February 25, 2025), are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Executive Order 14294

Section 5 of E.O. 14294 of May 9, 2025, ''Fighting Overcriminalization in Federal Regulations'' (90 FR 20367, May 14, 2025), directs that all future notices of proposed rulemaking (NPRMs) and final rules published in the **Federal Register**, the violation of which may constitute criminal regulatory offenses, should include a statement identifying that the rule or proposed rule is a criminal regulatory offense and the authorizing statute. E.O. 14294 directs agencies to draft this statement in consultation with the Department of Justice.

E.O. 14294 further directs that the regulatory text of all NPRMs and final rules with criminal consequences