BrachyFoam, Inc. d/b/a Advaray
% Dawn Norman, M.S.
Partner
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
CENTENNIAL, CO 80112

August 22, 2023

Re: DEN220052
Trade/Device Name: BrachyGel Vaginal Hydrogel Packing System
Regulation Number: 21 CFR 892.5735
Regulation Name: Vaginal hydrogel packing system
Regulatory Class: Class II
Product Code: QXR
Dated: August 25, 2022
Received: August 26, 2022

Dear Dawn Norman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the BrachyGel Vaginal Hydrogel Packing System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The BrachyGel Vaginal Hydrogel Packing System is a single-use, non-sterile, disposable, non-powered positioning device that delivers self-expanding hydrogel that forms and expands within the vaginal cavity. The purpose of this device is to displace the vaginal wall and adjacent pelvic tissues during radiation therapy planning and delivery, to reduce dose to adjacent tissues by attenuation of radiation dose, and to stabilize radiation treatment equipment during radiation therapy planning and delivery. The placement of the hydrogel device requires a physician or physician directed healthcare professional, and is performed as a separate procedure outside of brachytherapy applicator insertion, computed tomography and/or magnetic resonance imaging exam, radiation treatment planning and radiation treatment delivery. This device is not intended to be inserted into the uterine cavity or rectum. This device is intended to be in place temporarily and removed after less than 24 hours.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the BrachyGel Vaginal Hydrogel Packing System, and substantially equivalent devices of this generic type, into Class II under the generic name vaginal hydrogel packing system.

FDA identifies this generic type of device as:

> **Vaginal hydrogel packing system**. 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 26, 2022, FDA received your De Novo requesting classification of the BrachyGel Vaginal Hydrogel Packing System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BrachyGel Vaginal Hydrogel Packing System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request and provided interactively in response to interactive deficiencies, FDA has determined that, for the previously stated indications for use, the BrachyGel Vaginal Hydrogel Packing System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Unintended irradiation of healthy tissue and/or underdosing of the target	Clinical performance data Performance testing Labeling
Tissue damage from device instability, failure, or removal	Clinical performance data Non-clinical performance testing Labeling
Infection	Sterilization validation Non-clinical performance testing Labeling 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 Labeling
Patient discomfort	Clinical performance data Labeling

In combination with the general controls of the FD&C Act, the vaginal hydrogel packing system is subject to the following special controls:

(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 3-dimensional (3D) 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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety

and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the vaginal hydrogel packing system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Justina Tam at 240-402-4974.

Sincerely,

for

Robert Ochs, Ph.D.
Director
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health