DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

RadiaDyne, LLC
% Mr. Mark A. Heller
Goodwin Procter LLP
Counselors at Law
901 New York Avenue, NW
WASHINGTON DC 20001

Re: K132194 – Order Granting the Request for De Novo Classification
Prostate Immobilizer Rectal Balloon
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 892.5720
Regulation Name: Rectal Balloon for Prostate Immobilization
Regulatory Classification: Class II
Product Code: PCT
Dated: July 15, 2013
Received: July 15, 2013

Dear Mr. Heller:

This letter corrects our letter dated January 28, 2014.

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 Prostate Immobilizer Rectal Balloon, a prescription device under 21 CFR Part 801.109, with the intended use of

> The RadiaDyne Prostate Immobilizer Rectal Balloon is a single use disposable, inflatable, non-powered positioning device intended for use in the temporary positioning of the rectal wall and adjacent structure in the male human anatomies. The purpose of the device is to stabilize the prostate during Computed Tomography (CT) exam and X-ray, when these imaging techniques are used for Radiation Therapy (RT) planning. The placement of the balloon requires a Physician or a Physician directed healthcare professional, and is performed as a separate procedure apart from the standard CT exam and RT treatment.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Prostate Immobilizer Rectal Balloon, and substantially equivalent devices of this generic type, into class II under the generic name "rectal balloon for prostate immobilization."

FDA identifies this generic type of device as: rectal balloon for prostate immobilization.

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.

Section 513(f)(2) of the Federal 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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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** classifying the device type.

On July 15, 2013, FDA received your de novo requesting classification of the Prostate Immobilizer Rectal Balloon into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Prostate Immobilizer Rectal Balloon 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, FDA has determined that the Prostate Immobilizer Rectal Balloon with the intended us of

> The RadiaDyne Prostate Immobilizer Rectal Balloon is a single use disposable, inflatable, non-powered positioning device intended for use in the temporary positioning of the rectal wall and adjacent structure in the male human anatomies. The purpose of the device is to stabilize the prostate during Computed Tomography (CT) exam and X-ray, when these imaging techniques are used for Radiation Therapy (RT) planning. The placement of the balloon requires a Physician or a Physician directed healthcare professional, and is performed as a separate procedure apart from the standard CT exam and RT treatment.

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.

FDA has identified the risks of rectal balloon for prostate immobilization as:

1. *Anorectal Toxicity*: Insertion of rectal balloon can cause adverse rectal tissue reaction on patients as a result of direct contact to the rectal mucosa. This reaction may also result

due to toxic, irritating, or sensitizing agents present in the rectal balloon formulation (allergic reaction).

2. *Tissue Damage*: Healthy tissue damage can result due to a lack of physical integrity of the rectal balloon. A lack of physical integrity of rectal balloon is a failure to perform the prostate immobilization due to low quality of material and substandard structural feature of the device. It can lead to adverse consequences to the patients such as leakage which can cause tissue toxicity from contamination, and balloon burst, which can cause local injury. Lack of physical integrity of the rectal balloon can also cause other mechanical and functional disorders.

3. *Perforation of the Rectum*: Perforation of the rectum may occur due to traumatic insertion of the rectal balloon. The improper direction of the rectal balloon tip and excessive force are likely the main causes of traumatic insertion of the rectal balloon. Over distending the rectal balloon can also lead to perforation. The bowel gas buildup can also contribute to perforation.

4. *Irradiation of Healthy Tissue*: Irradiation to healthy tissue can occur due to incorrect balloon placement. Incorrect balloon placement may be due to bowel gas build up, incorrect balloon insertion, or incorrect inflation of the balloon and may cause irradiation of healthy tissue and/or an inadequate (higher or lower) radiation dose delivered to the treatment target.

5. *Patient Intolerance*: Insertion of the rectal balloon can be intolerable to the patient. This intolerance can be due to any one or combination of the following factors: pain, irritation, anxiety, and any type of discomfort. This intolerance is further exacerbated by every repeated physical insertion of the rectal balloon and daily irradiation assault as the rectum and anus will become more sensitive after a series of radiation treatments and repeated insertion of rectal balloon. If the patient is unable to tolerate the balloon during any of the treatment sessions throughout the entire radiation treatment course, this may result in a need to re-plan the radiation treatment and/or delay the delivery of the radiotherapy.

Special controls are necessary to address the risks posed by this device and to provide a reasonable assurance of safety and effectiveness. In addition to the general controls of the FD&C Act, rectal balloon for prostate immobilization is subject to the following special controls:

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.

Table – Identified Potential Risks and Required Mitigation Measures

Identified Risks	**Required Mitigation Measures**
Anorectal Toxicity Insertion of rectal balloon can cause adverse rectal tissue reaction on patients as a result of direct contact to the rectal mucosa. This reaction may also result due to toxic, irritating, or sensitizing agents present in the rectal balloon formulation (allergic reaction).	Special controls (1)(i), (1)(ii), (1)(iii), (1)(iv), (2)(i)(*D*), (2)(ii), (2)(iii), and (2)(iv)
Tissue Damage Healthy tissue damage can result due to lack of physical integrity of the rectal balloon. A lack of physical integrity of rectal balloon is a failure to perform the prostate immobilization due to low quality of material and substandard structural feature of the device. It can lead to adverse consequences to the patients such as leakage which can cause tissue toxicity from contamination and balloon burst which can cause local injury. Lack of physical integrity of the rectal balloon can also cause other mechanical and functional disorders.	Special controls (1)(iv), (1)(v), (2)(i)(*A*), (2)(i)(*D*), (2)(ii), (2)(iii), and (2)(iv)
Perforation of the Rectum Perforation of the rectum may occur due to traumatic insertion of the rectal balloon. The improper direction of the rectal balloon tip and excessive force are likely the main causes of traumatic insertion of the rectal balloon. Over	Special controls (1)(v)(*A*), (1)(v)(*B*), (2)(i)(*A*), (2)(i)(*D*), (2)(ii), (2)(iii), and (2)(iv)

distending the rectal balloon can also lead to perforation. The bowel gas buildup can also contribute to perforation.	
Irradiation of Healthy Tissue Irradiation to healthy tissue can occur due to incorrect balloon placement. Incorrect balloon placement may be due to bowel gas build up, incorrect balloon insertion, or incorrect inflation of the balloon and may cause irradiation of healthy tissue and/or an inadequate (higher or lower) radiation dose delivered to the treatment target.	Special controls (1)(v)(*A*), (1)(v)(*B*), (2)(i)(*B*), (2)(ii), (2)(iii), and (2)(iv)
Patient Intolerance Insertion of the rectal balloon can be intolerable to the patient. This intolerance can be due to any one or combination of the following factors: pain, irritation, anxiety, and any type of discomfort. This intolerance is further exacerbated by every repeated physical insertion of the rectal balloon and daily irradiation as the rectum and anus will become more sensitive after a series of radiation treatments and repeated insertion of rectal balloon. If the patient is unable to tolerate the balloon during any of the treatment sessions throughout the entire radiation treatment course, this may result in a need to re-plan the radiation treatment and /or delay the delivery of the radiotherapy.	Special controls (1)(v)(*A*), (2)(i)(*A*), (2)(i)(*C*), (2)(ii), (2)(iii), and (2)(iv)

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 rectal balloon for prostate immobilization they intend to market prior to marketing the device and receive clearance to market from FDA.

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 market your device, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Amarjeet Singh Bhullar, Ph.D. at (301) 796-5917 or Amarjeet.bhullar@fda.hhs.gov.

Sincerely yours,

For

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health