DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Myriad Medical, LLC
% Mr. Frank Bimbo
Medical Device Consultant
1535 Carrington Court
LAWRENCEVILLE GA 30044

March 31, 2015

Re: K150234
Trade/Device Name: Myriad Prostate Caddy™ Immobilization Rectal Balloon Item #9901,3301
Regulation Number: 21 CFR 892.5720
Regulation Name: Rectal balloon for prostate immobilization
Regulatory Class: II
Product Code: PCT
Dated: December 21, 2014
Received: February 2, 2015

Dear Mr. Bimbo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K-150234

Device Name

Myriad Prostate Caddy™ Immobilization Rectal Balloon Item #9901,3301

Indications for Use *(Describe)*

The Myriad Prostate Caddy™ Immobilization 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510K PREMARKET SUBMISSION SUMMARY K150234
for SUBSTANTIAL EQUIVALANCE - PROSTATE IMMOBILIZER RECTAL BALLOON

1. **Regulatory Information:**

   a. **Identification**

   FDA identifies this type of device as:

   Rectal Balloon for Prostate Immobilization

   The 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. **Regulatory Number: 21 CFR 892.5720**

   c. **Classification: II**

   d. **Product Code: PCT**

2. Background:

   a. **Submitter's Information:**

Submitter's Name:	Myriad Medical
Address:	2202 N. West Shore Blvd. Suite 200 Tampa, FL 33607
Contact Person	Frank Bimbo
Contact Person's Phone:	1 770 630 7028
Contact Person's Mobile:	1 770 630 7028
Contact Person's Fax:	1 404 935 0995
Date of Preparation:	November 21, 2014

   b. **Device Name:**

Trade Name:	Prostate Caddy™ Immobilization Device
Common/Usual Name:	Myriad Rectal Balloon
Classification Name:	Prostate Immobilization Rectal Balloon

   c. **Predicate device Name/Number:**

Trade Name:	RadiaDyne Prostate Immobilizer Rectal Balloon RB Classic Series (without a gas release valve)
510K Number:	K132194

   d. **Requester's Recommended Classification:** Class II

3. Indications for Use:

The Myriad Prostate Caddy™ Immobilization 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.

4. Device Description:

a. <u>Device Description</u>: The Myriad Prostate Caddy™ Immobilization Rectal Balloon , as in **figure 1,** is designed as an immobilizer to assist in positioning the prostate in a more predictable and reproducible location during Computed Tomography (CT) exam and X-ray, when these imaging techniques are used for Radiation Therapy (RT) planning. The Prostate Immobilization Rectal Balloon is inserted into the rectum and inflated prior to the start of a CT scan or RT therapy procedure. The device stabilizes the prostate once the device is inflated. The Prostate Immobilizer Rectal Balloon is deflated and removed after each individual scan or therapy procedure is complete, and a new balloon is used in the next therapy session. Myriad's device is designed for single use, is provided non-sterile to the end user, is not intended to be sterilized by the end user, and is packaged in a kit configuration. Each kit contains the following items: Rectal Balloon (PVC); Syringe (optional accessory to the device); Locking Stopper (accessory to the device) and the Instructions for Use. The balloon consists of a single lumen shaft with a blow molded balloon attached to the distal end of the shaft. The balloon is bonded to the shaft at the proximal end of the balloon. The shaft extends into the balloon but it is not attached at the end with a rounded atraumatic tip. Several eye holes are provided to inflate/deflation of the balloon. The main section of the device consists of a balloon and single lumen tubing which are made of PVC. The remainder of the device is made of other medical grade materials consisting of the following components shown below in **Table 1**.

Table 1 summarizes the comparison for the Technical Characteristics between the Submitted Device, Myriad Rectal Balloon and the Predicate Device, RadiaDyne Rectal Balloon. **Table 2** summarizes the Product Testing comparison between the Submitted Device and the Predicate Device. The Tables demonstrate the Substantial Equivalence of the two Products.

The device can be inflated with either air or water, and this process is carried out with the single use disposable syringe that is supplied (or offered as an option) with the device in the accessory kit. The locking stopper supplied with the Prostate Immobilizer Rectal Balloon controls the depth at which the balloon is inserted into the rectum. The device can therefore be locked into place once inserted into place.

b. <u>Principle of Operation</u>: 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. The balloon is inserted in the patient's rectum and inflated with air or water using the syringe. Standard imaging and treatment protocols are to be used to verify the device placement and adjust the stopper depth until the desired device position is obtained. The balloon is intended to

stabilize the prostate and displace normal tissue away from the radiation treatment area. Stabilization of the prostate is intended to allow more consistent treatment targeting and delivery of radiation to tumor only. The displacement of normal tissue is intended to reduce unnecessary radiation exposure and reduce side effects from radiation treatment.

c. Modes of Operation: The device can be used to stabilize the prostate during Computed Tomography (CT) exam and X-ray, when these imaging techniques are used for radiation Therapy (RT) planning.

d. Accessories: The device is packaged in a kit configuration with the following items: Rectal Balloon, Syringe (optional), Stopper and Instructions for Use.

5. Summary of Nonclinical/Bench Studies

Nonclinical performance was performed to address the following areas. The Studies conducted are consistent with the predicate Device. The Testing Summary compared to the predicate device is provided in **Table 2.**

a. Biocompatibility/Materials:

Biocompatibility testing was submitted for the subject device which is intended for direct skin and/or mucosal membrane contact with the patient for less than 24 Hours. There is also the possibility for contact with breached or compromised skin/mucosal surface; as such the following testing was conducted at NAMSA, 6750 Wales Road, Northwood, Ohio 43619, for Cytotoxicity, Skin Irritation, Sensitization and Acute Systemic Toxicity per the appropriate standards and acceptance levels.

i) Cytotoxicity was evaluated based on the requirements of the International Organization for Standardization 10993-5, Biological evaluation of medical devices – Part 5: Test for *in vitro* cytotoxicity. The detailed results are contained in the Test Results and Review, **Attachment A**. Based on the review, additional testing was not considered to be warranted as the safety of the device has been supported by the data presented.

ii) Rectal Irritation was evaluated based on the requirements of the International Organization for Standardization 10993-10, Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization. For the test samples, the irritation index was 0 or no reaction. The SC (Sodium chloride) and SO (Sesame oil) test extracts were considered nonirritants to the rectal tissue of the rabbit model. The detailed report is contained in **Attachment B.**

iii) Sensitization was evaluated based on the requirements of the International Organization for Standardization 10993-10, Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization. There was no observed evidence of dermal reaction with all sites scoring a 0 reaction. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article (Myriad Prostate Balloon) was not considered a sensitizer in the guinea pig maximization test. The full report is contained in **Attachment C.**

iv) Acute Systemic Toxicity was evaluated based on the International Organization for Standardization 10993-11, Biological evaluation of medical devices, Part 11: Tests for systemic

toxicity. For the test subject and the control, there was no mortality, the animals appeared normal and all animals gained weight. There was no mortality or evidence of systemic toxicity from the extracts injected into the mice. The results showed no difference between the test and control animals. The full report is contained in **Attachment D.**

These tests adequately address the biocompatibility concerns for the subject device consistent with the predicate device.

b. Shelf Life/Sterility:

The sponsor has provided shelf-life testing data, which ensures that the subject device is within acceptable bioburden limits and device will function properly after 2 years of storage. Therefore, the shelf-life of Myriad Prostate Caddy™ Immobilization Rectal Balloon is declared on the label and is set at two years. Myriad has established a specification for a non-sterile device for rectal use under USP < 61> and USP <62> indicating for Total Aerobic count a limit of 1000 CFU/ g and for Fungi 100 CFU/g. This specification derives from the medical and scientific literature and the fact that the product is neither intended nor offered for sale as sterile, and is for use in the rectum, an anatomical cavity laden with bacteria and enormously high CFU counts. The detailed test results are provided in **Attachment E, VAL\04-MM032012ESR, Myriad Medical Engineering Study (ES) Protocol and Report,** Product Validation – Physical Testing & 2 Year Shelf Life Testing**.** The bioburden testing results are provided in **Attachment F.**

c. Electromagnetic Compatibility and Electrical Safety:

Not applicable

d. Software:

Not applicable

e. Performance Testing – Bench:

The following performance tests were performed:

- Bioburden Testing: Bioburden testing was conducted by NAMSA on the balloon, stopper, inside the lumen and the plunger. The testing process was repeated 3 times with an inoculums population of $3.4x10^2$ CFU. The processing method used resulted in a percent recovery of 99%. The Total Recoverable of Aerobic Bioburden was an average of 75 CFU with a maximum level of 168 CFU. The maximum acceptable limit is 1000 CFU. The Total Recoverable Fungi Bioburden was an average for 4 CFU with a maximum level of 8 CFU. The maximum acceptable limit is 100 CFU. The Bioburen results are well within acceptable limits. The detailed results are contained in the report in **Attachment F**.

- Leakage Testing: The product was validated for Leakage under VAL\04-MM032012ESR, Myriad Medical Engineering Study (ES) Protocol and Report, **Attachment E**. A statistically appropriate number of devices were inflated with 100cc of water, (10% more than the recommended inflation) and held at that pressure for a minimum of 10 minutes. All units passed Leak Testing.

In addition, all devices are subject to leak testing as the final quality control check. 100 % of the Balloons are inflated and held under pressure before they are released to inspection. Devices that pass the leak test are accepted for final processing to finished goods.

- Tensile-strength and Burst-strength Testing (in air): The product was validated for Burst-strength and Tensile-strength under VAL\04-MM032012ESR, Myriad Medical Engineering Study (ES) Protocol and Report, **Attachment E**. The Balloons were burst tested with H_2O under the Leak Testing. In addition, the Balloons were tested for Burst and Tensile with air to assure the durability and integrity of the assembly of the product. The Balloons were inflated to 100cc of air and Tensile Tested through a ½" orifice until the Balloon withstood 7.1 Lbs. of force. The force of 7.1 Lbs simulates a worst case usage of the product in the rectum (per the literature) plus a safety factor. All of the balloons passed the test with no signs of burst, leakage or joint failure. The test was repeated for the 2-Year Shelf Life Testing with no failures.

- Stopper Resistance Testing: The Stopper resistance to movement and proper locking were tested under VAL\04-MM032012ESR, Myriad Medical Engineering Study (ES) Protocol and Report, **Attachment E**. The Stopper was locked in place and tested for resistance to movement. Based on literature, the Stopper must withstand a tensile force of 3.57 Lbs. The force to move the Stopper had an average value of 4.91 lbs. All of the units passed the test.

The performance testing was consistent with the predicate device in all aspects. The performance of the product exceeded the requirements established. The testing for performance showed that the Myriad Prostate Caddy™ Rectal Balloon performed as intended and meets Customer expectations.

6. Discussion of Equivalency

K150234 is being submitted by Myriad Medical, LLC for their Prostate Caddy™ Immobilization Device to demonstrate equivalency to a predicate device, RadiaDyne Classic Rectal Balloon under K132194. The principle of operation, product description and Indications for Use are identical to the predicate device. The instructions for use include all of the appropriate warnings and contraindications, adequate instructions for insertion, sterility or non-sterility and expiration date. And, the technical characteristics are equivalent to the predicate device. Myriad Medical has completed all of the testing submitted for the predicate device. This submission contains all of the data demonstrating that Myriad Balloon has successfully passed biocompatibility, shelf life, product performance testing and structural integrity (e.g., tensile strength, balloon leakage and burst strength) comparable to the RadiaDyne Classic Balloon. The data contained in the report supports information provided for the customer in the instructions for use and the labeling. In addition, Myriad Medical has applied the labeling, required mitigation measure and special controls established for the predicate device. Finally, Myriad Medical has not requested or indicated any product claims different than the predicate device.

7. Conclusion

Myriad Medical, LLC respectively believes that the requirements have been met to determine that the Myriad Rectal Balloon is substantially equivalent to the predicate device, RadiaDyne Classic Rectal Balloon under K132194. The data contained in the submission shows that the product will perform as intended and will meet customer expectations. The Myriad submission, K150234, provides reasonable assurance of the safety and efficacy of the device.