November 13, 2018

QLRAD International Ltd.
℅ Audrey Swearingen
Regulatory Affairs Specialist
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
AUSTIN, TX 78746

Re: K180478
Trade/Device Name: RectalPro™ 75 Endorectal Balloon
Regulation Number: 21 CFR 892.5720
Regulation Name: Prostate Immobilizer Rectal Balloon
Regulatory Class: Class II
Product Code: PCT
Dated: October 11, 2018
Received: October 12, 2018

Dear Mr. Swearingen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. Ochs, Ph.D.
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)*
K180478

Device Name
RectalPro™75 Endorectal Balloon

Indications for Use *(Describe)*
The RectalPro™75 Endorectal Balloon device is a single-use disposable, inflatable, non-powered positioning device intended for us 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.

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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510(k) Summary

RectalPro™75 Endorectal Balloon

K180478

1. Submission Sponsor

QLRAD International Ltd. (QLRAD)

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Contact: Arjen Winkel

Title: President and CEO

2. Submission Correspondent

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Office Phone: (512) 327.9997

Contact: Audrey Swearingen

Title: Regulatory Affairs Manager

3. Date Prepared

February 21, 2018

4. Device Identification

Trade/Proprietary Name:	RectalPro™ Endo Rectal Balloon (ERB) (“RectalPro 75”)
Common/Usual Name:	Rectal Balloon for Prostate Immobilization
Classification Name:	Prostate immobilizer rectal balloon
Regulation Number:	21 CFR 892.5720
Product Code:	PCT
Device Class:	Class II
Classification Panel:	Radiology

5. Legally Marketed Predicate Device(s)

K150234, Myriad Prostate Caddy™ Immobilization Rectal Balloon Item, Myriad Medical, LLC

6. Indication for Use Statement

The RectalPro™75 Endorectal Balloon device 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.

7. Device Description

The RectalPro™ 75 Endorectal Balloon (ERB) is single use, disposable, inflatable, non-powered rectal 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. The RectalPro75 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 ERB 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 ERB is deflated and removed after each individual scan or therapy procedure is complete, and a new balloon is used in the next therapy session.

The RectalPro ERB is designed with a slim curved, extended shaft and balloon. The device is provided non-sterile to the end user, is not intended to be sterilized by the end user. It is packaged in a kit configuration, consisting of three primary components:

1. ERB shaft – This is the shaft with attached balloon and attached clear plastic tubing for filling the balloon with air / water. The end of the tubing has a female luer lock. There are white markings on the side of the ERB shaft as insertion depth markings.

2. Stopper – This is the circular plastic piece with one flat side, and one side containing four prongs. There is a hole in the middle of the stopper for placement onto the ERB shaft.

3. Air / water valve – This is the small plastic valve on the air tube connected to the ERB shaft. The clamp on the air / water tube stops the air / water flow by squeezing the tube closed. This component stops air / water from releasing out of the balloon after it has been filled.

The kit also includes a standard 100 cc syringe with male luer lock connector, for connecting to the female luer connection of the ERB tubing, and is used to deliver the water or air to the ERB.

8. Substantial Equivalence Discussion

The following table compares the RectalPro™75 Endorectal Balloon to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance.

The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**QLRAD International Ltd.**	**Myriad Medical, LLC**	**Device Comparison**
Trade Name	**RectalPro™75 Endorectal Balloon**	**Myriad Prostate Caddy™ Immobilization Rectal Balloon**	
510(k) Number	To be determined	K150234	Not applicable
Product Code	PCT	PCT	Same
Regulation Number	21 CFR 892.5720	21 CFR 892.5720	Same
Regulation Name	Rectal balloon for prostate immobilization	Rectal balloon for prostate immobilization	Same
Indications for Use	The RectalPro™75 Endorectal Balloon device 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 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	Similar Indications statements. The intended use to immobilize / stabilize the prostate during radiation therapy is the same for both.

Manufacturer	**QLRAD International Ltd.**	**Myriad Medical, LLC**	**Device Comparison**
Trade Name	**RectalPro™75 Endorectal Balloon**	**Myriad Prostate Caddy™ Immobilization Rectal Balloon**	
		standard CT exam and RT treatment.	
Mechanism of Action	The balloon is inserted in the patient's rectum and inflated with air or water using the syringe. The stopper is used to lock the device at the desired depth. The balloon is intended to stabilize the prostate and displace normal tissue away from the radiation treatment area.	The balloon is inserted in the patient's rectum and inflated with air or water using the syringe. The stopper is used to lock the device at the desired depth. The balloon is intended to stabilize the prostate and displace normal tissue away from the radiation treatment area.	Same
Device Components	Rectal balloon attached to Curved Shaft, with protective sleeve; Locking Stopper; Tubing, Syringe	Rectal balloon attached to Shaft, no protective sleeve; Locking Stopper; Tubing; Syringe	Same basic components and configuration. RectalPro 75 has a protective sleeve on the balloon to protect it during handling and transportation; RectalPro shaft is curved on the end to assist insertion into the rectum. These minor design changes do not raise new questions of safety and effectiveness.
Inflated Diameter	4.5 cm with 60cc air 4.6 cm with 80cc air 5.0 cm with 100cc air	4.6 cm with 80cc air 5.0 cm with 100cc air	Same
Gas Venting Valve	No	None verified	Not known. The RectalPro ERB is open-ended to allow release of gas.

Manufacturer	**QLRAD International Ltd.**	**Myriad Medical, LLC**	**Device Comparison**
Trade Name	**RectalPro™75 Endorectal Balloon**	**Myriad Prostate Caddy™ Immobilization Rectal Balloon**	
Visualization Method	CT / MRI	CT / MRI	Same
Sterilization	Not provided sterile nor intended to be sterilized	Not provided sterile nor intended to be sterilized	Same
Single Use	Yes	Yes	Same
Shelf Life	2.5 years	2 years	Similar
Patient Contacting Materials	PVC with Blue colorant; Silicone; Polypropylene	PVC; 'polymer'; Other materials unknown	All materials used in the manufacture of the RectalPro75™ Endorectal Balloon are suitable for this use and have been used in numerous previously cleared products. The materials were tested per ISO 10993 and found to be biocompatible.
Non-Clinical Bench Testing	Bioburden - < 100CFU Leakage (water) – no leaking with 110cc water after 60 min; Tensile (Burst) (air) – did not burst with 140cc air under 7.7 lbs force for 12 min.; Stopper Resistance - stopper did not move under 10 lbs of force	Bioburden - < 100CFU Leakage (water) – no leaking with 100cc water after 10 min; Tensile (Burst) (air) – did not burst with 100cc air under 7.1 lbs force; Stopper Resistance – force required to move was 4.91 lbs average	The performance testing was consistent with the predicate device. The results showed that the RectalPro™75 Endorectal Balloon performed as intended and is at least as safe and effective as the predicate.

9. Non-Clinical Performance Data

In demonstrating safety and effectiveness of RectalPro™75 Endorectal Balloon, and in showing substantial equivalence to the predicate device, QLRAD International Ltd. performed various assessments. The RectalPro™75 Endorectal Balloon meets the requirements for design and

functionality, with test results confirming that the design output meets the design inputs and specifications for the device, and performs comparably to the predicate device.

The RectalPro™75 Endorectal Balloon was assessed for the following in accordance with internal requirements and international standards, and met all requirements:

- Biocompatibility per ISO 10993-1. Device determined to be biocompatible.
- Bioburden testing per ANSI/AAMI/ISO 11737-1. Device met acceptance criteria.
- Leak and Burst testing per internal protocol. Device met acceptance criteria.
- Transportation testing per ASTM D4169:2016. Device met requirements.
- Risk assessment per ISO 14971. Device has acceptable residual risks.

10. Statement of Substantial Equivalence

The device has the same intended use and the same or similar technological characteristics to the Prostate Caddy Balloon predicate device. The differences do not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

Therefore, the RectalPro™75 Endorectal Balloon is determined to be substantially equivalent to the predicate device.