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U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

VIA UNITED PARCEL SERVICE

JULY 20, 2017

Arjen Winkel
President and CEO
QLRAD Netherlands
Rietveldstraat 22
Zwolle, Overijssel, NETHERLANDS 8013 RW

Re: FDA Reference Number COR13000320

Dear Mr. Arjen Winkel,

The United States Food and Drug Administration (FDA) has learned that your firm, QLRAD Netherlands (QLRAD), is marketing the RectalPro Endorectal Balloon (ERB)

in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

FDA has reviewed your website at (http://qlrad.com/products/endo-rectal-balloon/) and your brochures for these devices distributed at the American Society for Radiation Oncology (ASTRO) conferences held in San Antonio, Texas (2015) and in Boston, MA (2016). We have determined that the RectalPro Endorectal Balloon device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The RectalPro Endorectal Balloon deviceis also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution this device without submitting a premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

In response to a de novo request under section 513(f)(2) of the Act, in 2014 FDA classified rectal balloons for prostate immobilization in class II, subject to special controls and 510(k) premarket notification. (See https://www.accessdata.fda.gov/cdrh_docs/pdf13/K132194.pdf). FDA has not yet codified this order in the Code of Federal Regulations (CFR), but one other device has been cleared in a 510(k) as substantially equivalent to the device that was the subject of the de novo request. (See https://www.accessdata.fda.gov/cdrh_docs/pdf15/K150234.pdf). To be legally marketed, a device of this type must both comply with the special controls and be found substantially equivalent to a legally marketed predicate device of this type.

Although there is a 510(k) exemption for manual gastroenterology-urology surgical instruments and accessories under 21 CFR 876.4730, your device is not exempt because it is intended for a use different from those of legally marketed devices in this generic category. Generic devices of this type are intended to be used for gastroenterological and urological surgical procedures. However, based on evidence obtained from your website and brochures as of July 20, 2017, your firm is marketing the RectalPro Endorectal Balloon for a different intended use, namely to immobilize the prostate in patients undergoing radiation therapy. Particularly, your firm’s website and brochures explain that the balloon is intended to “immobilize the prostate, facilitating the reduction of clinical target volume margins, reducing dose delivered to

normal tissues … [and] displaces the lateral and posterior rectal walls from regions of high dose" away from the radiation treatment area. This is intended to more "consistently stabilize[] the prostate [and] prevent[] … displacement" to "accurately target the prostate and reduce radiation dose to the rectum." The displacement of normal tissue is intended to reduce risk of unnecessary radiation exposure and "limit side effects" from the radiation treatment. Thus, when using QLRAD RectalPro Endorectal Balloon to immobilize the prostate during external beam prostate radiotherapy, the balloon becomes a major component in the pre-treatment set-up and targeting apparatus in a high dose, high risk radiation therapy procedure.The new intended use raises a series of new safety concerns related to anorectal toxicity, tissue damage, perforation of the rectum, irradiation of healthy tissue and patient intolerance. Because there is evidence that the RectalPro Endorectal Balloon deviceis intended for uses that are different from those of legally marketed devices classified under 21 CFR 876.4730, it exceeds the limitations described in 21 CFR 876.9(a) and is not exempt from premarket notification.

In communications with the FDA regarding submitting a 510(k) for the RectalPro Endorectal device, your letter dated 12/26/2014 communicated to FDA that "**(b)(4)**. Your email dated 01/20/2016 includes a **(b)(4)**. Your email dated 09/27/2016 states that **(b)(4)**. Your email dated 12/22/2016 states **(b)(4)**. However, as of the date of this **(b)(4)**. In addition, your email dated 12/2/2015 communicated to FDA that the product was in the United States, but was not being marketed. However, based on evidence that we have collected, you are actively marketing the RectalPro Endorectal device for use in radiation therapy.

The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/defaul FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our office requests that QLRAD immediately cease commercial distribution of these devices for the uses discussed above that have not been cleared or approved by FDA, which causes them to be adulterated and misbranded.

Given the serious nature of the violations of the Act, RectalPro Endorectal Balloon is subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter.

Please notify this office in writing within fifteen (15) business days from the date you

receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
Attn: OIR/DRH/NMRT Branch
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Please refer to COR13000320 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Division of Radiological Health, Division Director Dr. Robert Ochs at 301-796-6661.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Sincerely yours,
/S/
Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue
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1-888-INFO-FDA (1-888-463-6332)

Contact FDA