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

November 18, 2014

Edge Medical LLC
% Mr. Gregory Mathison
President
Regulatory Strategies, Inc.
3924 Cascade Beach Road
LUTSEN MN 55612

Re: K141958
Trade/Device Name: ERB Endorectal Balloon
Regulation Number: 21 CFR 892.5720
Regulation Name: Rectal balloon for prostate immobilization
Regulatory Class: II
Product Code: PCT
Dated: September 11, 2014
Received: September 16, 2014

Dear Mr. Mathison:

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,

for

Janine M. Morris
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)*
K141958

Device Name
ERB

Indications for Use *(Describe)*

The ERB 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Attachment 6

510(k) Summary

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

APPLICANT:	Edge Medical, LLC
TRADE NAME:	ERB
COMMON NAME:	Endorectal Balloon
CLASSIFICATION NAME:	Rectal Balloon for Prostate Immobilization, 21 CFR 892.5720
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE:	PCT
PREDICATE DEVICES:	RadiaDyne Prostate Immobilizer Rectal Balloon (K132194)
CONTACT	Greg Mathison Regulatory Affairs
DATE:	July7, 2014

Substantially Equivalent to:

The ERB is equivalent in intended use, principal of operation and technological characteristics to the RadiaDyne Prostate Immobilizer Rectal Balloon (K132194).

Description of the device subject to premarket notification

The ERB 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 ERB is designed for single use, is provided non-sterile to the end user, and is not intended to be sterilized by the end user. The ERB consists of a balloon and tubing can be inflated with either water or air. The device can be locked into place once inserted into the rectum with a locking stopper.

Indications for Use
The ERB 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.

Materials

All materials used in the manufacture of the ERB are suitable for this use and have been used in numerous previously cleared products. The ERB materials were tested per ISO10993 and found to be biocompatible. Testing included the following:

- Cytotoxicity
- Sensitization
- Irritation

Non-Clinical Testing

Product testing was completed and met all of the acceptance criteria. Testing included dimensional, visual, mechanical and performance.

Performance Data:
All necessary verification and validation testing has been performed for the ERB to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the ERB is determined by Edge Medical, to be substantially equivalent to existing legally marketed devices.

Comparison of Product Features

Trade name	Device (Edge Medical System)	RadiaDyne Prostate Immobilizer Rectal Balloon	SE Discussion
Product code	PCT	PCT	Same product code - PCT
510k number	-	K132194	
Device Classification	II	II	Same – Class II
Device description	The ERB is designed as an immobilizer to assist in positioning the prostate in a more predictable and	The RadiaDyne Prostate Immobilizer Rectal Balloon is designed as an immobilizer to assist in positioning the	The device description is the same.

	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. Visual and radiopaque markers aid placement. The ERB is meant to stabilize the prostate once it is inflated. The ERB is deflated and removed after each individual scan or therapy procedure is compete, and a new balloon is used in the next therapy session. ERB is designed for single use, is provided non-sterile to the end user, and is not intended to be sterilized by the end user.	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 Immobilizer Rectal Balloon is inserted into the rectum and inflated prior to the start of a CT scan or RT therapy procedure. Visual and radiopaque markers aid placement. 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 compete, and a new balloon is used in the next therapy session. RadiaDyne's device is designed for single use, is provided non-sterile to the end user, and is not intended to be sterilized by the end user.	
Intended Use	The ERB 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.	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.	Same Indications for Use
Length	Balloon: 10cm; Device: 30cm	Balloon: 9cm; Device: 20cm	The small differences in the balloon length does not affect the safety or efficacy of the device's ability to immobilize the prostate.
Diameter	4.6cm	Balloon: 3.9cm when inflated	The diameter difference does not affect the safety of the device as the inflation of both devices is within typical anatomical patient differences.
Deflated	0.38cm	0.32cm	The diameters are equivalent

insertion diameter			for the insertion of the device to the target area.
Method of visualization	X-ray	X-ray	Same
Conforming treatment length	10cm	9cm	The treatment length is slightly longer for the subject device. As stated previously, the lengths are within patient anatomical variability. Therefore, the safety profile of both devices is equivalent.
Sterilization	None	None	Both devices are supplied non-sterile.
Single use	Y	Y	Same
Shelf life	180 days after production	Not indicated in submission	This will be on the product label
Packaging	Tyvek / nylon pouch. IFU on 8”x11” paper.	Tyvek / nylon pouch. IFU on 8”x11” paper.	Same
Materials	Biocompatible	Biocompatible	The Edge Medical device materials were tested to the ISO10993 standard and found to be biocompatible. As the RadiaDyne Prostate Immobilizer Rectal Balloon device was reviewed and cleared by FDA, we assume the materials of construction for the RadiaDyne Prostate Immobilizer Rectal Balloon are biocompatible as well.

Conclusion

The products are substantially equivalent as the indications for use are the same, the clinical application is the same, the materials are equivalent, the dimensions are equivalent and the tested product performance attributes are equivalent.