DxTx Medical, Inc.
% Paul Lawson
Director of Quality and Regulatory
DxTx Medical Inc.
639 Alpha Dr
PITTSBURGH PA 15238

February 10, 2023

Re: K223249
Trade/Device Name: Pro-Tx Endorectal Balloon (PROT-25)
Regulation Number: 21 CFR 892.5720
Regulation Name: Rectal Balloon For Prostate Immobilization
Regulatory Class: Class II
Product Code: PCT
Dated: September 7, 2022
Received: October 21, 2022

Dear Paul Lawson:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.02.10 06:58:50 -05'00'

Lora D. Weidner, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223249

Device Name

Pro-Tx Endorectal Balloon (PROT-25)

Indications for Use *(Describe)*

The DxTx Medical Pro-Tx Endorectal Balloon is a disposable, single use non-powered inflatable positioning device intended to be used for temporary positioning of the rectal wall and adjacent structures in the male human anatomies and to assist in positioning the prostate in a more predictable and reproducible location.

The purpose of the DxTx Medical Pro-Tx Endorectal Balloon is to stabilize the rectal wall and surrounding anatomy during all phases of radiation therapy, including treatment planning, image verification, and radiotherapy delivery. Only trained healthcare professionals are intended to operate this device.

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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510(k) Summary

Pro-Tx Endorectal Balloon

K223249

I. Sponsor Information

DxTx Medical, Inc.
ATTN: Paul Lawson
639 Alpha Drive
Pittsburgh, PA 15238

Phone: 412-596-3221
Email: paul.lawson@dxtxmedical.com
https://dxtxmedical.com/

II. Date of 510(k) Preparation:

January 12, 2023

III. Subject Device:

Trade name:	Pro-Tx Endorectal Balloon
Common Name:	Rectal balloon for prostate immobilization
Classification Name:	Prostate Immobilizer Rectal Balloon
Regulation number:	21 CFR 892.5720
Product Code:	PCT
Regulatory class:	II
Review Panel:	Radiology

IV. Predicate Device

De Novo Number:	DEN130036
510(k) Number:	K132194
Trade name:	RadiaDyne Prostate Immobilizer Rectal Balloon
Common Name:	Rectal balloon for prostate immobilization
Classification Name:	Prostate Immobilizer Rectal Balloon
Regulation number:	21 CFR 892.5720
Product Code:	PCT
Regulatory class:	II
Review Panel:	Radiology

V. Device Description

The DxTx Medical Pro-Tx Endorectal Balloon is a disposable, single use device for immobilization and localization of the rectal wall and surrounding anatomy on a daily basis for radiation therapy treatment. The Pro-Tx Endorectal Balloon includes the shaft and inflatable balloon with a gas venting feature. The Pro-Tx Endorectal Balloon is capable of being filled with air or fluid. The intended contact duration of the device is less than 60 minutes.

No components of this device contain medicinal substances, tissues or blood products.

The device component materials are PVC, Polycarbonate, Polyethylene, Polypropylene, Copolyester, Liquid Silicone Rubber (balloon), and brass (the radiopaque marker).

VI. Intended Use / Indications for Use

The DxTx Medical Pro-Tx Endorectal Balloon is a disposable, single use non-powered inflatable positioning device intended to be used for temporary positioning of the rectal wall and adjacent structures in the male human anatomies and to assist in positioning the prostate in a more predictable and reproducible location.

The purpose of the DxTx Medical Pro-Tx Endorectal Balloon is to stabilize the rectal wall and surrounding anatomy during all phases of radiation therapy, including treatment planning, image verification, and radiotherapy delivery. Only trained healthcare professionals are intended to operate this device.

VII. Summary of Technological Characteristics Compared to Predicate Device

The intended use and principles of operation of the DxTx Medical Pro-Tx Endorectal Balloon and the RadiaDyne RB Classic Prostate Immobilizer Rectal Balloon predicate device are substantially equivalent. Both devices meet the regulatory definition for Prostate Immobilizer Rectal Balloon outlined in 21 CFR 892.5720.

Both devices stabilize the rectal wall and surrounding anatomy during all phases of radiation therapy, including treatment planning, image verification, and radiotherapy delivery. Only trained healthcare professionals are intended to operate this device.

Feature	Predicate Device De Novo Number: DEN130036/ 510(k) Number: K132194	DxTx Medical Device Pro-Tx Endorectal Balloon
Indications for Use	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	The DxTx Medical Pro-Tx Endorectal Balloon is a disposable, single use non-powered inflatable positioning device intended to be used for temporary positioning of the rectal wall and adjacent structures in the male human anatomies and

Feature	Predicate Device De Novo Number: DEN130036/ 510(k) Number: K132194	DxTx Medical Device Pro-Tx Endorectal Balloon
	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.	to assist in positioning the prostate in a more predictable and reproducible location. The purpose of the DxTx Medical Pro-Tx Endorectal Balloon is to stabilize the rectal wall and surrounding anatomy during all phases of radiation therapy, including treatment planning, image verification, and radiotherapy delivery. Only trained healthcare professionals are intended to operate this device.
Size	Similar to Pro-Tx	17" long, shaft outer diameter 0.3"
Technology Characteristics	Soft Tip Thin Wall Balloon Fiducial marker Semi-flexible shaft Depth markers on shaft Depth stopper Flexible syringe connector tubing Rapid release valve (balloon fill and empty) Gas release vent Gas release valve (GRB Series only, not on RB Classic Series: Allows controlled release of rectal gas after balloon insertion	Soft Tip Thin Wall Balloon Fiducial marker Semi-flexible shaft Depth markers on shaft Depth stopper Flexible syringe connector tubing Rapid release valve (balloon fill and empty) Gas release vent No gas release valve – Rectal gas automatically vents out
Accessories	100 ml Syringe Lubricant	No accessories – customer provides their own; Luer lock interfaces with off the shelf syringes
Safety	No product related hazards were reported in the FDA MAUDE database since the product was approved in January 2014 to 31 July 2022 MR Conditional for tantalum fiducial marker	No product related hazards were reported in the FDA MAUDE database for the Bayer Pro-Tekt, which is the design for the Pro-Tx transferred to DxTx Medical, since the initial distribution agreement in August 2010 to 31 July 2022 MR Conditional for brass fiducial marker
Effectiveness	Performance Tests (from De Novo): Bioburden Leakage Tensile strength Burst strength Depth stopper resistance Vent	Performance Tests Bioburden Leakage (Inflation Integrity) Tensile strength (Axial Pull) Burst strength Depth stopper resistance Vent (Occlusion) 3' Drop 45º Shaft Flexure
Material	Thin Wall Balloon: Polyurethane Fiducial marker: Tantalum	Thin Wall Balloon: Silicone (equivalent function) Fiducial marker: Brass (equivalent function)
Energy Source	Non-powered; hand syringe-inflated	Non-powered; hand syringe-inflated

The minor technological differences between DxTx Medical Pro-Tx Endorectal Balloon and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that DxTx Medical Pro-Tx Endorectal Balloon is as safe and effective as RadiaDyne Prostate Immobilizer Rectal Balloon predicate device. Thus, DxTx Medical Pro-Tx Endorectal Balloon is substantially equivalent.

VIII. Summary of Data to Support Substantial Equivalence

The determination of substantial equivalence was based on an assessment of non-clinical performance data obtained from biocompatibility and bench testing of the subject device to demonstrate the ability to meet the Special Controls in 21 CFR 892.5720.

Biocompatibility

The DxTx Medical Pro-Tx Endorectal Balloon was based on the MEDRAD/Bayer HealthCare-designed Pro-Tekt Endorectal Balloon, which was on the market since 2010; the design for the latter was transferred to DxTx Medical. The biocompatibility characteristics for all Pro-Tx product components, manufacturing materials and methods were evaluated with no issues identified. The post-market performance of the legacy Pro-Tekt device had no documented safety issues. Therefore, there are no biocompatibility risks with the Pro-Tx device.

Shelf-life

A box of 25 Pro-Tx devices was subjected to 2 year accelerated aging by an independent ISO 17025-certified lab, after which the devices were inspected, and bench tested to demonstrate 2 year shelf life equivalent to the predicate device.

Performance Verification (Bench Testing)

The following tests were completed to demonstrate performance equivalent to the predicate device and in compliance with 21 CFR 892.5720: Axial pull tests, inflation integrity, burst strength, occlusion (vent function) test, drop test and flexure test.

IX. Conclusion

The DxTx Medical Pro-Tx Endorectal Balloon has a safety and effectiveness profile that is similar to the predicate device. In particular, the subject device has the same or similar indications, technological characteristics, and principles of operation as the predicate device. The minor differences between the two devices do not raise any new issues of safety and effectiveness when the device is used as labeled. Therefore, it can be concluded that the DxTx Medical Pro-Tx Endorectal Balloon is substantially equivalent to the predicate device.