July 17, 2025

DxTx Medical, Inc.
Paul Lawson
Director of Quality and Regulatory, R&D Manager
639 Alpha Dr
Pittsburgh, Pennsylvania 15238

Re: K243428
Trade/Device Name: e^{2}Coil^{TM} Imaging System for the Siemens MAGNETOM 3.0T MRI Systems with Tim 4G Connector
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: June 11, 2025
Received: June 12, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ningzhi Li -S

Digitally signed by Ningzhi Li -S

for
Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243428

Device Name
e^2Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI Systems with Tim 4G Connector

Indications for Use *(Describe)*

Probe: The DxTx e^2Coil probes are recommended for high-resolution magnetic resonance imaging, including spectroscopy, of the prostate and surrounding pelvic tissue in the male human anatomies and are specifically designed for use with the appropriate e^2Coil Interface Device and Intermediate Cable Assembly. The one-time use, disposable e^2Coil probe has been designed to be inserted into the human rectum. The e^2Coil probe may be inserted by a trained healthcare professional, depending on state or country law, who has training in e^2Coil probe insertion.

Interface Device: The Siemens 3.0T Endo Interface II with Tim 4G SlideConnect (e^2Coil™) provides interface and support functions to allow the use of 3.0T disposable e^2Coil probes with Siemens 3.0T MRI Systems with a Tim 4G connector. 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

K243428

e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI Systems with Tim 4G Connector

I. Sponsor Information

DxTx Medical, Inc.
639 Alpha Drive
Pittsburgh, PA 15238

Contact Person: Paul Lawson
Phone: 412-435-3867
Email: paul.lawson@dxtxmedical.com
https://dxtxmedical.com/

Date of 510(k) Preparation: July 14, 2025

II. Subject Device:

Trade name:	e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI Systems with Tim 4G Connector
Common Name:	Prostate Endo Coil
Classification Name:	Coil, Magnetic Resonance, Specialty
Regulation number:	21 CFR 892.1000
Product Code:	MOS
Regulatory class:	II
Review Panel:	Radiology

III. Predicate Device

510(k):	K051349
Trade name:	3.0T Prostate Imaging System
Common Name:	Prostate Endo Coil
Classification Name:	Coil, Magnetic Resonance, Specialty
Regulation number:	21 CFR 892.1000
Product Code:	MOS
Regulatory class:	II
Review Panel:	Radiology

IV. Device Description

The e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI Systems with Tim 4G Connector is a combination of the following two devices for improving the diagnostic MR image of the prostate and its surrounding pelvic tissues:

- Siemens 3.0T Endo Interface Gen II with Tim 4G Slide Connect (e²Coil)
- Endorectal MRI Coil II for 3.0T MR Imaging of the Prostate (e²Coil) – Siemens
  - Coil contains two loops and four channels

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 patient contacting device component materials are Latex, PVC, and Polymer.

V. Intended Use / Indications for Use

Probe: The DxTx e²Coil probes are recommended for high-resolution magnetic resonance imaging, including spectroscopy, of the prostate and surrounding pelvic tissue in the male human anatomies and are specifically designed for use with the appropriate e²Coil Interface Device and Intermediate Cable Assembly. The one-time use, disposable e²Coil probe has been designed to be inserted into the human rectum. The e²Coil probe may be inserted by a trained healthcare professional, depending on state or country law, who has training in e²Coil probe insertion.

Interface Device: The Siemens 3.0T Endo Interface II with Tim 4G SlideConnect (e²Coil™) provides interface and support functions to allow the use of 3.0T disposable e²Coil probes with Siemens 3.0T MRI Systems with a Tim 4G connector. Only trained healthcare professionals are intended to operate this device.

VI. Summary of Technological Characteristics Compared to Predicate Device

The intended use and principles of operation of the e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI Systems with Tim 4G Connector and the DxTx Medical (formerly MEDRAD/Bayer) 3.0T Prostate Imaging System predicate device are substantially equivalent. Both devices meet the regulatory definition for Coil, Magnetic Resonance, Specialty outlined in 21 CFR 892.1000.

Only trained healthcare professionals are intended to operate this device.

The technological differences between the e²Coil™ and its predicate eCoil raise no new issues of safety or image quality effectiveness.

Feature	Predicate Device	DxTx Medical Device System
	Trade Name: 3.0T Prostate Imaging System **Model Numbers:** 08624855 (Interface Device), BPX 30 (Disposable Probe) **510(k) Holder:** DxTx Medical, Inc. (transferred from Bayer Healthcare in 2019) **510(k) Number:** K051349	**Trade Name:** e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI Systems with Tim 4G Connector **Device Model Numbers - Trade Names in System:** 4000518 - Siemens 3.0T Endo Interface Gen II with Tim 4G Slide Connect (e²Coil) BPX 30 NG-S - Endorectal MRI Coil II for 3.0T MR Imaging of the Prostate (e²Coil) – Siemens
Indications for Use	The 3.0T Siemens Prostate Imaging System ("the device") is part of the Prostate Imaging Offerings from DxTx and is intended for use as a Magnetic Resonance Diagnostic Device (MRDD) for high-resolution magnetic resonance imaging, including spectroscopy, of the human prostate gland and surrounding pelvic tissue. The disposable eCoil Endorectal Coil (eCoil) is intended for one time use and is specifically designed to be used with an appropriate interface device. The 3.0T Siemens Prostate Imaging System is intended for use with Siemens 3.0T Tim Trio scanner platforms only. Only trained healthcare professionals are intended to operate this device. The 3.0T Siemens Prostate Imaging System is comprised of the Siemens Interface Device and the 3.0T eCoil (eCoil).	Probe: The DxTx e²Coil probes are recommended for high-resolution magnetic resonance imaging, including spectroscopy, of the prostate and surrounding pelvic tissue in the male human anatomies and are specifically designed for use with the appropriate e²Coil Interface Device and Intermediate Cable Assembly. The one-time use, disposable e²Coil probe has been designed to be inserted into the human rectum. The e²Coil probe may be inserted by a trained healthcare professional, depending on state or country law, who has training in e²Coil probe insertion. Interface Device: The Siemens 3.0T Endo Interface II with Tim 4G SlideConnect (e²Coil™) provides interface and support functions to allow the use of 3.0T disposable e²Coil probes with Siemens 3.0T MRI Systems with a Tim 4G connector. Only trained healthcare professionals are intended to operate this device.
Size	Interface Device with cable: 28 ¼" long BPX 30 disposable coil: 25" long	Interface Device with cable + Intermediate Cable 38 ¼" Disposable coil: 14 ½"
Technology Characteristics	Soft Tip Thin Wall Balloon Semi-flexible shaft Depth stopper Flexible syringe connector tubing One coil (loop) in disposable coil One channel	Soft Tip Thin Wall Balloon (same part as BPX 30) Semi-flexible shaft (same part as BPX 30) Depth stopper (same part as BPX 30) Flexible syringe connector tubing (same part as BPX 30) Two coils (loops) in disposable coil Four channels
Accessories	50-60 ml Syringe	50-60 ml Syringe Intermediate Cable
Safety	No product related hazards were reported in the FDA MAUDE database in the most recent Post Market	Equivalent low-risk safety design

Feature	Predicate Device	DxTx Medical Device System
	Surveillance Report 01-Oct-2019 to 30-Sep-2023 Coil Biocompatibility MR ≤ 3.0T Conditional	Coil is the same mechanically as BPX 30 so has the same biocompatibility MR ≤ 3.0T Conditional The disposable coil includes a fuse as an additional level of electrical protection, which the predicate system does not.
Effectiveness	Performance Tests: Scanner Validation on Siemens 3.0T Skyra MR scanner Coil Leakage, Tensile strength, Burst strength, Depth stopper resistance	Performance Tests: Scanner Validation on Siemens 3.0T Skyra MR scanner Coil is the same mechanically as BPX 30 so has the same mechanical performance
Material	Thin Wall Double Balloon: Natural Latex	Thin Wall Balloon: Same balloon
Energy Source	MR scanner	MR scanner

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Endorectal MRI Coil II for 3.0T MR Imaging of the Prostate (e²Coil) was conducted in accordance with FDA Guidance 635 "Immunotoxicity Testing Guidance" May 6, 1999 and International Standard ISO 10993-1:2018 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" as recognized by the FDA. The battery of testing includes the following tests:

- Cytotoxicity
- Irritation
- Sensitization.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI, consisting of the Siemens 3.0T Endo Interface Gen II with Tim 4G Slide Connect and the Endorectal MRI Coil II for 3.0T MR Imaging of the Prostate. The system complies with the IEC 60601-1 standard for EMC.

Mechanical testing

Mechanical strength for portable equipment testing, consisting of the following listed tests, was conducted on the e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI, consisting of the Siemens 3.0T Endo Interface Gen II with Tim 4G Slide Connect and the Endorectal MRI Coil II for 3.0T MR Imaging of the Prostate:

- Push
- Impact
- Drop
- Moulding Stress Relief

The system complies with the IEC 60601-1 standard for mechanical strength.

MR Safety testing

MR safety testing was conducted on the e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI, consisting of the Siemens 3.0T Endo Interface Gen II with Tim 4G Slide Connect and the Endorectal MRI Coil II for 3.0T MR Imaging of the Prostate. The system is MR Conditional compliant to the 3.0T environment per IEC 60601-2-33.

SNR testing

Signal to Noise Ratio (SNR) testing was conducted on the e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI, consisting of the Siemens 3.0T Endo Interface Gen II with Tim 4G Slide Connect and the Endorectal MRI Coil II for 3.0T MR Imaging of the Prostate. The SNR using the e²Coil™ Imaging System was consistently higher than the SNR of the scanner body coil alone on the Siemens 3.0T Skyra scanner per NEMA MS 1 2.3.2.4 Method 4.

Uniformity testing

Signal uniformity testing was conducted on the e²Coil™ Imaging System for the Siemens MAGNETOM 3.0T MRI, consisting of the Siemens 3.0T Endo Interface Gen II with Tim 4G Slide Connect and the Endorectal MRI Coil II for 3.0T MR Imaging of the Prostate. The signal showed good uniformity per NEMA MS 3 and IEC 62464-1 in the axial, coronal, and sagittal axes.

VIII. Conclusion

The DxTx e²Coil is designed to have safety and effectiveness substantially equivalent 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.