



July 25, 2025

Leo Cancer Care
% Nickie Power
Head of Regulatory and Quality
7921 UW Health Court
MIDDLETON, WI 53562

Re: K250970
Trade/Device Name: Marie
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: March 31, 2025
Received: June 30, 2025

Dear Nickie Power:

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,

A handwritten signature in black ink that reads "Lu Jiang" is positioned over a large, light blue, semi-transparent watermark of the letters "FDA".

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K250970

Device Name

Marie

Indications for Use (Describe)

The Marie Imaging System is indicated for the acquisition of CT images and the precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate therapy treatment delivery 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.

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Traditional 510(k) SUMMARY

Leo Cancer Care Marie System

I. SUBMITTER

Leo Cancer Care Inc
7921 UW Health Court
Middleton WI 53562
USA

Contact:

Nickie Power

Nickie.Power@leocancercare.com

Establishment Registration #

3017500061

510(k) Number:

K250970

Date:

28 March 2025

II. DEVICE

Trade Name:

Marie

Product Classification:

Class II

Common Name:

CT Imaging and Patient Positioning System (for use with external Beam Treatment delivery system)

Regulation Number:

21 CFR 892.1750

Regulation Description:

Computed tomography x-ray system

Product Code:

JAK

III. PREDICATE

Predicate device:

P-ARTIS K160611

Regulation Number:

21 CFR 892.1750 (Computed Tomography X-ray System)

Product Code:

JAK

IV. INDICATIONS FOR USE

The Marie Imaging System is indicated for the acquisition of CT images and the precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate therapy treatment delivery device.

V. DEVICE DESCRIPTION

The Marie System is intended to acquire CT images and enable the precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate therapy treatment delivery device.

The Marie System is intended to be used by healthcare professionals to image patients in an upright position rather than conventional supine treatments, to enable precise treatment planning and patient positioning for radiotherapy.

Specifically, it is intended to:

- Image the patient to provide image-guided radiation therapy
- Image the patient to acquire images for the purpose of treatment planning
- Immobilize patients in an upright position for upright radiotherapy.

The Marie System is comprised of two major sub-systems: a computed tomography (CT) imaging system that performs pretreatment imaging and treatment simulation in the upright positions and a beam agnostic, patient positioning system that supports the patient in the upright positions.

The Marie Imaging System is used with compatible devices for treatment delivery and patient immobilization. The positioning system is designed with six degrees of freedom of motion and a patient positioning system to provide the desired posture for each cancer site to achieve accurate, reproducible patient setups, while the imaging system acquires helical scans by translating and rotating up the patient.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Characteristic	Leo Cancer Care Marie system	P-Cure P-ARTIS System – K160611
Intended Use	The Marie Imaging System is indicated for the acquisition of CT images and the precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate therapy treatment delivery device.	The P-ARTIS CT scanner is a Computed Tomography X-Ray System intended to produce images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. The system may include signal analysis and display equipment, patient, and equipment supports, components and accessories. The system is intended for scanning patients while seated
Indications for Use	The Marie Imaging System is indicated for the acquisition of CT images and the precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate therapy treatment delivery device.	The P-ARTIS CT scanner is a Computed Tomography X-Ray System intended to produce images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. The system may include signal analysis and display equipment, patient, and equipment supports, components and accessories. The system is intended for scanning patients while seated
CT scanner	Acquire CT images of patients to facilitate delivery of external beam radiation	Acquire CT images of patients to facilitate delivery of external beam radiation
Image Acquisition	Axial and Multi-slice helical scanning, 2D/3D reconstruction	Axial and Multi-slice helical scanning, 2D/3D reconstruction
Imaging system central bore diameter	84 cm	85 cm
Image resolution at 120kV, 250mA	4.0 lp/cm @ 50% MTF 7.9 lp/cm @ 10% MTF 10.0 lp/cm @ 2% MTF	4.3 lp/cm @ 50% MTF 8.0 lp/cm @ 10% MTF 15.0 lp/cm @ 0% MTF
Image Slice Thickness	0.625, 1.0, 2.0, 4.0, 5.0 mm	2.0, 3.0, 4.0, 5.0, 8.0 mm
Field of View	62cm	60cm
Imaging Angle	0-15 degrees	20 degrees
Gantry Scan Plane	Up and down over patient	Up and down over patient

Patient load (maximum)	150 kg	375 kg
Patient Positioning Motion axis	6 degrees of freedom	Same as predicate
Motion drives	Computer controlled, servo motor based multi axis motion system.	Robotic positioning system (Computer controlled, servo motor system)
Patient orientation	Chair based patient support	Patient table couch or other approved patient support device
Speed	X: 0 – 50mm/sec Y: 0 – 50mm/sec Z: 0 – 25mm/sec Pitch & Roll: 2 degrees per sec 360 rotation: 6 degrees per sec	0.1 m/s and 6 degrees per sec
Accuracy	X: ± 0.3 mm Y: ± 0.3 mm Z: ± 0.7 mm Iso-rotation: ± 0.1 deg. Pitch & Roll: ± 0.5 deg	± 0.5 mm and ± 0.2 degrees
Rotation	Full 360-degree rotation	Full 360-degree rotation
Patient support range of pitch	The backrest has 15-degrees from vertical	Support table has ± 15 degrees of pitch

VII. SUMMAY OF PERFORMANCE TESTING (NON-CLINICAL)

Design verification and performance testing were carried out in accordance with design controls of FDA’s Quality System Regulation (21 CFR §820.30), applicable ISO 13485 Quality Management System requirements, ISO 14971 risk management requirements, IEC 62304 requirements for software life-cycle processes, and FDA guidance1.

Non-clinical testing was performed to evaluate device performance and functionality against design and risk management requirements at sub-system and system levels. Leo Cancer Care utilised the test methods and performance criteria outlined in the table below to demonstrate performance to current guidance.

Source	Performance Requirements
AAPM REPORT NO. 233 - Performance Evaluation of Computed Tomography Systems	<ul style="list-style-type: none"> - <i>HU Accuracy</i> <ul style="list-style-type: none"> o <i>Water: ± 7 HU</i> o <i>Acrylic: ± 10 HU</i> o <i>Polyethylene: ± 10 HU</i> o <i>Bones: ± 60 HU</i> o <i>Air: ± 17 HU</i> - <i>Image uniformity ± 15 HU</i> - <i>Geometric Efficiency >70%</i>
Quality assurance for image-guided radiation therapy utilizing CT-based technologies: A report of the AAPM TG-179	<ul style="list-style-type: none"> - <i>Image resolution Line pairs: ≥10 lp/cm</i>
Quality assurance for computed-tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66	<ul style="list-style-type: none"> - <i>Contrast to Noise: ≥1.0</i> - <i>Spatial Integrity (in-plane): ± 1 mm over at least 100 mm</i>

Software verification testing was conducted and documented in accordance with FDA guidance for “Enhanced Documentation”, (Class C per IEC 62304).

Basic safety and essential performance have been satisfied through conformance with recognized consensus standards for medical devices listed below.

Standard	Title
ISO 14971:2019 Third Edition 2019-12	<i>Medical Devices – Application of risk management to medical devices</i>
IEC 60601-1: Edition 3.2, 2020	<i>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</i>
IEC 60601-2-68: Edition 1.0, 2014	<i>Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators light ion beam therapy equipment and radionuclide beam therapy equipment</i>
IEC 60601-2-44: Edition 3.2, 2016	<i>Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography</i>
IEC 60601-1-2 Edition 4.1 (2020-09)	<i>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances -- Requirements and tests</i>
IEC 62304:2016	<i>Software life-cycle processes</i>
IEC 60601-1-6:2020 Edition 3.2	<i>Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability</i>
ANSI AAMI IEC 62366-1:2020 Edition 1.1	<i>Medical Devices – Part 1: Application of Usability Engineering to Medical Devices</i>

VIII. SUBSTANTIAL EQUIVALENCE CONCLUSION

The Marie System is substantially equivalent to the predicate devices in terms of intended use and technological characteristics. The devices safety and performance have been addressed by non-clinical testing in conformance with pre-determined performance criteria, FDA guidance, and recognized consensus standards.

The differences between Marie System and the predicate device raise no new efficacy or safety concerns.