Leo Cancer Care
% Graham Lukey
Regulatory Affairs Management Contractor
7921 UW Health Court
MIDDLETON, WI 53562

May 7, 2024

Re: K231612
Trade/Device Name: Eve Patient Positioner System
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered Radiation Therapy Patient Support Assembly
Regulatory Class: Class II
Product Code: JAI
Dated: March 29, 2024
Received: March 29, 2024

Dear Graham Lukey:

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.

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231612

Device Name

EVE Patient Positioner System

Indications for Use *(Describe)*

The Leo Cancer Care Patient Positioning Subsystem is indicated for precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate beam 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K231612

Traditional 510(k) SUMMARY
Leo Cancer Care Eve Patient Positioning Subsystem

I. SUBMITTER

	Leo Cancer Care Inc 7921 UW Health Court Middleton WI 53562 USA
Contact:	Graham Lukey
	Graham@leocancercare.com
Establishment Registration #	3017500061
510(k) Number:	K231612
Date:	8 September 2023

II. DEVICE

Trade Name:	Leo Cancer Care Eve Patient Positioning Subsystem
Product Classification:	Class II
Common Name:	Patient Positioner (for use with external Beam Treatment delivery system)
Regulation Number:	21 CFR 892.5770
Regulation Description:	Couch, radiation therapy, powered
Product Code:	JAI

III. PREDICATE

Predicate device: LEONI Orion System K160518

IV. INTENDED USE

The Leo Cancer Care Patient Positioning Subsystem is indicated for precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate beam therapy treatment delivery device.

V. DEVICE DESCRIPTION

The Leo Cancer Care (LCC) Patient Positioning Subsystem (EVE) is designed to deliver precise positioning of a patient when combined with an external Beam Therapy device, to provide the intended treatment therapy prescribed for patients requiring radiation treatments.

The Patient Positioning System has 6 degrees of freedom to provide full alignment capability for a patient treatment session, with the patient being located in an upright position. The Eve Patient Positioning Subsystem is held in a static position for the duration of the external Beam Therapy System radiation exposure. After the beam delivery has been completed, the patient positiong subsystem is then aligned to the next patient position required by the treatment system and the process repeated for the required series of different beam placements to achieve the full prescribed treatment delivery for the patient.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Characteristic	**Leo Cancer Care Eve** system	LEONI **Orion System** – K160518
Intended Use	The Leo Cancer Care Patient Positioning Sub-system is indicated for precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate beam therapy treatment delivery device.	The LEONI ORION System is an electro-mechanical robotic arm for patient positioning in radiotherapy, radiology and other medical applications. It is designed for positioning a patient with a high degree of accuracy and repeatability.
Indications for Use	The Leo Cancer Care Patient Positioning Sub-system is indicated for precise positioning of human patients to facilitate delivery of external beam radiation when integrated with a separate beam therapy treatment delivery device.	The LEONI ORION System is an electro-mechanical robotic arm for patient positioning in radiotherapy, radiology and other medical applications. It is designed for positioning a patient with a high degree of accuracy and repeatability.
Patient load (maximum)	150 kg	375 kg
Motion axis	6 degrees of freedom	6 degrees of freedom

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: ±0.3mm Y: ±0.3mm Z: ±0.7mm Iso-rotation: ±0.1deg. Pitch & Roll: ±0.5deg	+/-0.5mm and +/- 0.2 degrees
Rotation	Full 360-degree rotation	Full 360-degree rotation
Patient support range of pitch	The backrest has 30-degrees of tilt motion in 5-degree increments	Support table has +/- 15 degrees of pitch
Alignment geometry	Chair coordinate system configured relative to treatment system coordinate system requirement	Chair coordinate system configured relative to treatment system coordinate system requirement

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. Software verification testing was conducted and documented in accordance with FDA guidance for devices that pose a major level of concern (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	*Medical Devices – Application of risk management to medical devices*
IEC 60601-1: Edition 3.2, 2020	*Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
IEC 60601-1-2 Edition 4.1 (2020-09)	*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances -- Requirements and tests*
IEC 62304:2019	*Software life-cycle processes*
IEC 60601-1-6:2020 Edition 3.2	*Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
ANSI AAMI IEC 62366-1:2020 Edition 1.1	*Medical Devices – Part 1: Application of Usability Engineering to Medical Devices*

VIII. SUMMARY OF PERFORMACE TESTING (CLINICAL)

No animal or clinical tests were performed to establish substantial equivalence with the predicate device. The performance data demonstrate that EVE Patient Positioner System is as safe and effective and performs as well as the predicate device.

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

The Eve Patient Positioning 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 the Eve Patient Positioning System and the predicate device raise no new efficacy or safety concerns.