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

July 14, 2016

LEONI CIA Cable System SAS
% Ms. Aurelie Genho
Quality Engineer
5 Avenue Victor Hugo
28000 Chartres
FRANCE

Re: K160518
Trade/Device Name: LEONI Orion System
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: JAI
Dated: July 5, 2016
Received: July 7, 2016

Dear Ms. Genho:

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

Robert Ochs, Ph.D.
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)*
K160518

Device Name
LEONI Orion System

Indications for Use *(Describe)*
The LEONI Orion System in an electro-mechanical robotic arm for patient positioning in radiotherapy and medical imaging. It is designed for positioning a patient with a high degree of accuracy and repeatability.

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

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

Applicant	LEONI CIA Cable Systems SAS 5, avenue Victor Hugo ZAC du Jardin d'Entreprises 28000 CHARTRES France
Contact person	Mrs. Aurélie GENHO Ph : +33 2 37 91 21 82 Fax : +33 2 37 91 21 81
Preparation Date	January 29, 2016
Device Name	Common Name: LEONI ORION System Trade Name: LEONI ORION System
Classification Name	Powered radiation therapy patient support assembly (21 CFR 892.5770) Product Code: JAI
Substantial Equivalence	Patient Positioning System by Forte Automation Systems (K122413)
Device Description	The LEONI ORION System is an electro-mechanical robotic arm capable of motion in six degrees of freedom. The purpose of the device is to position a patient during radiotherapy, radiology and other medical applications with a high degree of accuracy and repeatability. The LEONI ORION System consists of the electro-mechanical unit that is a 6 axes robot which supports a standard radiotherapy table couch or other approved patient support device, and a Control Unit that includes computers and application software. The robot is linked to the Control Unit by cables.
Intended Use	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.

Comparison of Technological Characteristics with the Predicate Device

The LEONI ORION System is identical or similar to the predicate device in regard to:

- Intended Use
- Shape, dimensions and materials
- Behavior and technology of movement
- Safety features

The LEONI ORION System has the following technological differences compared with the predicate device:

- Rotational axis linked to the floor
- Greater range of motion thanks to its hybrid kinematic and the length of the axes
- A higher payload capacity
- A UPS battery that allows the slow release of the brakes in order to lower the couch into a safe position to remove the patient in case of power failure.

Non clinical Tests

The bench tests below were carried out by LEONI in support of the substantial equivalence determination:

- Payload: 375 kg / 826 lbs.
- Accurate treatment volume : 400 mm x 1000 mm x 500 mm
- Accuracy: ± 0.5 mm and ± 0.2°
- Speed: 0.1 m/s and 6 °/s
- Safety: collision detection: detection of a 150N force; “overtravel” in case of emergency stop: < 5 mm.

Moreover, electromagnetic compatibility (EMC) and electrical and mechanical safety tests were performed by third party test organization.

Clinical Tests

Not Applicable

Testing Conclusions

The results from these performance assessments demonstrated that the LEONI ORION System met the acceptance criteria defined in the product specifications. Moreover these results proved that the subject device is comparable to the predicate device in terms of safety and effectiveness performance.