Chinan Biomedical Technology, Inc.
℅ Mr. James Chinan Chen
CEO
6F., No.16, Sec.2 ,Shengyi Rd., Zhubei City
Hsinchu County, 302
TAIWAN (R.O.C)

June 27, 2019

Re: K182683
Trade/Device Name: Z-Robot™ Patient Positioning System
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: Class II
Product Code: JAI
Dated: May 10, 2019
Received: May 20, 2019

Dear Mr. Chen:

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 and Part 809**)**; 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182683

Device Name
Z-Robot™ Patient Positioning System

Indications for Use *(Describe)*
The Z-Robot™ Patient Positioning System is 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.

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

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Department of Health and Human Services
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"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."

Section 5

510(k) Summary

510(k) SUMMARY

5.1. Type of Submission: Traditional

5.2. Date of Summary: Sep. 25, 2018

5.3. Submitter:

Address:	Chinan Biomedical Technology, Inc. 6F., No.16, Sec. 2, Shengyi Rd., Zhubei City, Hsinchu County 302, Taiwan (R.O.C.)
Phone:	+886-3-5509118
Contact:	James Chinan Chen (chinan777@gmail.com)

5.4. Identification of the Device:

Proprietary/Trade name:	Z-Robot™ Patient Positioning System
Model Name:	Z-KR360
Classification Product Code:	JAI
Regulation Number:	892.5770
Regulation Description:	Powered radiation therapy patient support assembly
Review Panel:	Radiology
Device Class:	II

5.5. Identification of the Predicate Device:

Predicate Device Name:	LEONI Orion System
Manufacturer:	LEONI CIA Cable Systems SAS
Classification Product Code:	JAI
Regulation number:	892.5770
Device Class:	II
510(k) Number:	K160518

5.6. Intended use

The Z-Robot™ Patient Positioning System is 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.

5.7. Device description

The Z-Robot™ Patient Positioning System (hereinafter referred to as Z-Robot™) is an electro-mechanical robotic arm with the motion capability in six degrees of freedom. These axes allow the couch to be precisely positioned translationally and rotationally within the specified movement limits. Therefore, Z-Robot™ could be used to accurately position patient in radiotherapy and medical imaging.

5.8. Non-clinical testing

A series of safety and performance tests were conducted on the subject device, Z-Robot™ Patient Positioning System.

- Reliability test
- Software Validation test
- Electromagnetic compatibility and electrical safety test

  The Z-Robot™ Patient Positioning System complies with IEC 60601-1 standard for safety.
- Performance test

  To ensure proper performance in this application, the design input requirements direct that the final products must demonstrate the following properties:
  - Speed Accuracy
  - Translational Accuracy
  - Rotational Accuracy
  - Repeatability

  All test results were acceptable per the acceptance criteria detailed in the corresponding protocol and test report.

5.9. Clinical testing

No clinical test data was used to support the decision of substantial equivalence.

5.10. Substantial equivalence determination

Item	Subject device	Predicate device	Substantially equivalence
Proprietary Name	Z-Robot™ Patient Positioning System	LEONI Orion System	-
Model Name	Z-KR360	-	-
510(k) No.	-	K160518	-
Intended Use	The Z-Robot™ Patient Positioning System is 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.	The LBONI Orion System is 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.	Same
Type of use	Prescription Use	Prescription Use	Same
Payload	Rated payload of the robotic arm : 360 kg Maximum patient weight: 180 kg	375 kg	Differen[1]
Accurate treatment volume	400×1,000×500 mm	400×1,000×500 mm	Same
Accuracy	± 0.5 mm and ± 0.2°	± 0.5 mm and ± 0.2°	Same
Speed	• Linear XYZ maximal medical • speed: 10 cm/s • Linear XYZ maximum maintenance speed: 20 cm/s • Angular Yaw Pitch Roll maximum medical speed: 5 °/s • Angular Yaw Pitch Roll maximum maintenance speed: 12 °/s	• Linear XYZ maximal medical speed: 10 cm/s • Linear XYZ maximum maintenance speed: 20 cm/s • Angular Yaw Pitch Roll maximum medical speed: 5 °/s • Angular Yaw Pitch Roll maximum maintenance speed: 12 °/s	Same

Item	Subject device	Predicate device	Substantially equivalence
Safety			
Collision detection	Detection of a 150 N force	Detection of a 150 N force	Same
"Overtravel" in case of emergency stop	<5 mm	<5 mm	Same

Different[1]：Different but does not impact safety and effectiveness of subject device

5.11. Similarity and difference

The subject device has same intended use and similar performance as the predicate device. And the difference between the subject device and the predicate device is the payload. The subject device has undergone performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate device do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use and performance claims.

5.12. Conclusion

After analyzing bench tests, device description and intended use, it can be concluded that the Z-Robot™ Patient Positioning System is substantially equivalent to the predicate device.