Jiangsu Rayer Medical Technology Co., Ltd. May 1, 2020
℅ Peng Li
Quality Director
No. 99 Furongzhongsan Road, Xishan Economic Development Zone
Wuxi, Jiangsu 214192
CHINA

Re: K192405
Trade/Device Name: Image Guidance System for Radiotherapy
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: April 6, 2020
Received: April 9, 2020

Dear Peng Li:

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); 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
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192405

Device Name
Image Guidance System for Radiotherapy

Indications for Use *(Describe)*
Image Guidance System for Radiotherapy is intended to be used in combination with the radiotherapy device, for image-guided positioning verification and real-time tracking of target motion for patient radiation therapy. The Image Guidance System for Radiotherapy sends the positioning data or real-time tracking data to the radiotherapy device but does not control any part of the radiotherapy 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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192405

1. Date of Preparation

   4/29/2020

2. Sponsor Identification

   Jiangsu Rayer Medical Technology Co.,Ltd.

   No.99 Furongzhongsan Road, Xishan Economic Development Zone, 214192 Wuxi, PEOPLE'S REPUBLIC OF CHINA

   Establishment Registration Number: Not yet registered.

   Contact Person: Peng Li

   Position: Quality Director

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3. Designated Submission Correspondent

   Peng Li (Quality Director)

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Email:pli@rayertech.com

4. Identification of Subject device

Trade Name: Image Guidance System for Radiotherapy

Common Name: Patient Positioning System with respiratory Gating, Radiation Therapy, Charged-Particle, Medical

Models: IGTS, IGPS

Regulatory Information

Classification Name: System, Radiation Therapy, Charged-Particle, Medical

Classification: II

Product Code: IYE

Regulation Number: 21 CFR 892.5050

Review Panel: Radiology

Indications for Use:

The Image Guidance System for Radiotherapy is intended to be used in combination with the radiotherapy device, for image-guided positioning verification and real-time tracking of target motion for patient radiation therapy. The Image Guidance System for Radiotherapy sends the positioning data or real-time tracking data to the radiotherapy device but does not control any part of the radiotherapy device.

Device Description:

The product is a medical electrical device which is composed of hardware and software, and is jointly used with the radiation therapy device. Image Guidance System for Radiotherapy is intended to be used in combination with the radiotherapy device, for image-guided positioning verification and real-time tracking of target motion for patient radiation therapy.

5. Identification of Predicate Device

510(k) Number: K120789

Product Name: ExacTrac

Classification Name: System, Radiation Therapy, Charged-Particle, Medical

Classification: II

Product Code: IYE

Regulation Number: 21 CFR 892.5050

Review Panel: Radiology

6. Compatibility

The positioning feature of the subject device is compatible with Varian and Elekta linear accelerators and MASEP gamma ray stereotactic radiotherapy system. The real-time tracking feature is compatible with MASEP gamma ray stereotactic radiotherapy system. The subject device sends the positioning data or real-time tracking data to the radiotherapy device but does not control any part of the radiotherapy device.

The information of the compatible radiotherapy systems is provided as follows:

1) Gamma ray stereotactic radiotherapy

Device Name: ROTATING GAMMA SYSTEM INFINI (INFINI)

Model: INFINI

Manufacturer: MASEP Medical Science & Technology Development (Shenzhen) Co., Ltd.

510(k) Number: K102533

2) Linear accelerator

Device Name: TRILOGY SYSTEM WITH RAPIDARC

Model: Trilogy

Manufacturer: VARIAN MEDICAL SYSTEMS INC

510(k) Number: K072916

3) Linear accelerator

Device Name: ELEKTA SYNERGY, ELEKTA SYNERGY S AND XVIR3.5

Model: Synergy

Manufacturer: ELEKTA INC

510(k) Number: K051932

7. Couch Corrections for 6 Patient Offset Parameters

The compatible external couches used in most radiotherapy systems have no capability of rotation corrections. In the case of ignoring rotation angle couch correction parameters, the uncorrected rotation shifts may affect the clinical results. Therefore, it is recommended that the clinicians carefully evaluate the impact and make the right decision. It is also strongly recommended that the large rotations shall be corrected manually if the couch only receive and perform the 3 translation correction and ignore the 3 rotation parameters.

8. X-ray Exposure Technique for Radiation Dose Control

The subject device doesn't have ACE function. Instead, it has its own exposure technique. The imaging system in subject device devises an imaging scenario to achieve optimum image quality while minimizing radiation dose. The subject device also meets the safety requirement terms of IEC 60601-1-3 and IEC 60601-2-68 for controlling excessive radiation dose.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

- IEC 60601-1:2005 And A1:2012 Medical Electrical Equipment-Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-3:2013 Medical Electrical Equipment - Part 1-3: General Requirements for Basic Safety and Essential Performance -Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-2-68: 2014 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

- IEC 60601-2-28:2010 Medical Electrical Equipment-Part 2-8: Particular Requirements For The Basic Safety And Essential Performance of X-Ray Tube Assemblies For Medical Diagnosis
- IEC 60601-2-54:2009 Medical Electrical Equipment- Part 2-54: Particular Requirements For The Basic Safety And Essential Performance Of X-ray Equipment For Radiography And Radioscopy
- IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance-Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-1-6:2013 Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability
- IEC 62366-1:2015 Medical devices-Part 1: Application of usability engineering to medical devices

Bench testing summary

- Compatibility Testing with ROTATING GAMMA SYSTEM INFINI(INFINI)

The subject device is integrated with Masep's gamma ray head SRT system. The performance of the SRT system before and after the integration is compared to access the safety and effectiveness of the gamma ray SRT system.

The targeting accuracy of the integrated gamma ray SRT system is measured using end-to-end test. The targeting accuracy should be no larger than 1.0 mm.

The anthropomorphic target phantom is used to simulate the clinical process of real patient treatment, and test the targeting accuracy.

According to the test results, the targeting accuracy of Masep's gamma ray head SRT system after integration well meets the requirements for SRS. Its clinical process remains as effective as before integration. In summary, the integration of the subject device with Masep's gamma ray SRT system does not affect the performance of the gamma ray SRT system.

- Compatibility Testing with TRILOGY SYSTEM WITH RAPIDARC

  The subject device is integrated with Varian linear accelerator system. The performance of the linear accelerator system before and after the integration is compared to access the safety and effectiveness of the linear accelerator system.

  The targeting accuracy of the integrated linear accelerator system is measured using end-to-end test. The targeting accuracy should be no larger than 1.0 mm.

  Positioning accuracy comparison between the product and CBCT of the linear accelerator; targeting accuracy measurement for the integrated linear accelerator system.

  According to the test results, the positioning results of the subject devic and Varian OBI CBCT are highly consistent. The targeting accuracy of Varian Trilogy accelerator after integration well meets the requirements for SRS. Its clinical process remains as effective as before integration. In summary, the integration of the subject device with Varian Trilogy accelerator system does not affect the performance of the Varian Trilogy accelerator system.

- Compatibility Testing with ELEKTA SYNERGY, ELEKTA SYNERGY S AND XVIR3.5

  The subject device is integrated with Elekta linear accelerator system. The performance of the linear accelerator system before and after the integration is compared to access the safety and effectiveness of the linear accelerator system.

  The targeting accuracy of the integrated linear accelerator system is measured using end-to-end test. The targeting accuracy should be no larger than 1.0 mm.

  Positioning accuracy comparison between the product and CBCT of the linear accelerator; targeting accuracy measurement for the integrated linear accelerator system.

  According to the test results, the positioning results of the subject device and Elekta XVI CBCT are highly consistent. The targeting accuracy of Elekta Synergy accelerator after integration well meets the requirements for SRS. Its clinical process remains as effective as before integration. In summary, the integration of the subject device with Elekta Synergy accelerator system does not affect the performance of the Elekta Synergy accelerator system.

- Optical Guided Tracking Accuracy Testing

  The objective is to evaluate the optical tracking accuracy of the NDI unit under the worst

environmental conditions.

The 3D RMS volumetric accuracy acceptance criterion is 0.15 mm for extended pyramid volume.

The optical guided tracking accuracy is measured using a treatment couch to provide the translational shift as a reference.

According to the test results, the results of the tests performed under the worst environmental conditions show that the 3D RMS volumetric accuracy is 0.11 mm.

- System Positioning Accuracy Testing

The subject device provides two image registration approaches using bony structures and fiducial markers, respectively. The software exports 6 degrees of freedom positioning correction results, including three translational shifts and three rotational angles.

The overall positioning accuracy should be no larger than 1.0 mm, and the individual rotational angle accuracy should be no larger than 1.0°.

The subject device is installed with two types of flat panel detectors, CARERAY CareView 1800IF and PerkinElmer XRD 0840AN, respectively. Positioning accuracy of the subject device is tested using fiducial registration or bony structure registration algorithm with an anthropomorphic head phantom and a thoracic spine phantom. Measurements are performed using a treatment couch to provide the translational shifts as reference.

According to the test results, the subject device with either CARERAY CareView 1800IF or PerkinElmer XRD 0840AN flat panel detectors meet the testing criteria that the overall translational error is no larger than 1.0 mm, and the maximum of rotational errors is no larger than 1.0°.

- System Tracking Accuracy Testing

The objective is to evaluate the tracking accuracy for regular, irregular and sporadic respiratory motion under the worst environmental conditions.

The target tracking accuracy is better than 1.5 mm.

The tests are performed on the respiratory motion phantom with moving inserts, the phantom used for this test provides respiratory waveforms collected from clinical patient data.

According to the test results, the overall tracking error of the subject device, configured with either CARERAY CareView 1800IF or PerkinElmer XRD 0840AN flat panel detectors, is no larger than 1.5 mm, testing with both typical and irregular respiratory motion waveforms.

- System Performance Testing

The objective is to evaluate the specifications defined for the subject device.

a) The mechanical accuracy of the imaging center shall not exceed 0.5 mm.

b) The positioning accuracy shall not exceed 1.0 mm.

c) The positioning stability shall not exceed 0.3 mm.

d) For regular respiratory movement, the detection accuracy of the target movement caused by respiration shall not exceed 1.5 mm.

The performance testing described in this submission was performed according to existing manufacturer Standard Operation Procedure (SOP), protocols and pre-determined performance criteria.

According to the test results, all specifications of the subject device meets the requirement.

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Subject device	Predicate Device K120789
Product Code	IYE	IYE
Regulation Number	21 CFR 892.5050	21 CFR 892.5050
Class	II	II

Intended Use	The Image Guidance System for Radiotherapy is intended to be used in combination with the radiotherapy device, for image-guided positioning verification and real-time tracking of target motion for patient radiation therapy. The Image Guidance System for Radiotherapy sends the positioning data or real-time tracking data to the radiotherapy device but does not control any part of the radiotherapy device.	ExacTrac is intended to be used to place patients at an accurately defined pointed within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures, in order to treat lesions, tumors and conditions anywhere in the body when radiation treatment is indicated. ExacTrac may also be used to monitor the patient position during treatment.
Single Use	No	No
Sterility Condition	Non-sterile	Non-sterile
Patient-contact component	None	None
Positioning accuracy	≤1.0 mm	≤1.0 mm

The subject device and predicate device have the same functionalities, image-guided positioning and real-time tracking of target motion. Both devices have the same intended use. Therefore, the subject device is substantially equivalent to the predicate device.

12. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices.