March 18, 2025

Klarity Medical & Equipment (GZ) Co., Ltd.
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K241937
Trade/Device Name: Klarity SGRT System (ARSG-E1A, ARSG-E3A)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: June 24, 2024
Received: July 2, 2024

Dear Tracy Che:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241937

Device Name

Klarity SGRT System (ARSG-E1A, ARSG-E3A)

Indications for Use *(Describe)*

With radiotherapy equipment (Medical Linac, CT-Sim), it is used for patient positioning before treatment and continuous monitoring of patients during treatment, and can also be used to track patients' breathing mode (including DIBH, EEBH, 4DCT three breathing modes), in order to implement image acquisition synchronized with breathing and radiation therapy.

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 "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information

510 (k) owner's name:	Klarity Medical & Equipment (GZ) Co., Ltd.
Address:	No. 14, 3rd Street Shawan GETDD Guangzhou Guangdong 510730 China
Contact person:	Guohuang Zhou
Phone number:	+86 13580340561
Fax number:	/
Email:	zhgh@klarity-medical.com
Date of summary prepared:	2025-02-20

(2) Proprietary name of the device

Trade name/Model:	Klarity SGRT System/Models: ARSG-E1A, ARSG-E3A
Common name:	Medical charged-particle radiation therapy system.
Classification name:	Accelerator, Linear, Medical
Regulation number:	892.5050
Product code	IYE
Review panel:	Radiology
Regulation class:	Class II

(3) Predicate and reference device

Predicate device	
Sponsor	C-RAD POSITIONING AB
Device Name and Model	CATALYST
510(k) Number	K113276
Product Code	IYE
Regulation Number	892.5050
Regulation Class	Class II
Reference device	
Sponsor	C-RAD POSITIONING AB
Device Name and Model	SENTINEL, MODEL SP-001
510(k) Number	K082582

Product Code	IYE
Regulation Number	892.5050
Regulation Class	Class II

(4) Description/ Design of device

Klarity SGRT system offers a dedicated non-irradiating and non-invasive surface guided radiation therapy solution. SGRT system includes three main application modules: patient positioning, treatment (motion) monitoring and respiratory gating.

With the patient positioning module, the SGRT system continuously senses the 3D patient body surface and compares it with the prerecorded reference surface by 3D image registration; The calculated 6 degree-of-freedom positioning deviations are visualized and sent to the positioning couch, to ensure a consistent and efficient inter-session patient setup/positioning, both manually and automated.

With the treatment (motion) monitoring module, the SGRT system monitors the patient's surface in real-time throughout the treatment session. Once the body part surface exceeds the predefined tolerance, the system will automatically alert the therapist and turnoff the beam immediately.

With the respiratory gating module, the system keeps tracking the patient's respiratory movements in real-time. During the treatment delivery, this functionality is used to maximize the protection of organs-at-risk; And in CT room, this functionality is used to make the 4DCT imaging best adapt to the patient's breathing in order to minimize the 4DCT imaging artifacts caused by the respiratory motion.

Klarity SGRT system mainly consists of advanced software, PC workstation, one or three 3D cameras and calibration tools. SGRT system provides two models, ARSG-E1A and ARSG-E3A.

(5) Indications for Use

With radiotherapy equipment (Medical Linac, CT-Sim), it is used for patient positioning before treatment and continuous monitoring of patients during treatment, and can also be used to track patients' breathing mode (including DIBH, EEBH, 4DCT three breathing modes), in order to implement image acquisition synchronized with breathing and radiation therapy.

(6) Technological characteristics and substantial equivalence

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device**	**Remark**
510(k) Number	K241937	K113276	K082582	/
Trade name	Klarity SGRT System	Catalyst	SENTINEL, MODEL	/

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device**	**Remark**
			SP-001	
Manufacturer	Klarity Medical & Equipment (GZ) Co., Ltd.	C-Rad Positioning AB	C-Rad Positioning AB	/
Regulation number	21 CFR 892.5050	21 CFR 892.5050	21 CFR 892.5050	Same
Product code	IYE	IYE	IYE	Same
Device classification	Class II	Class II	Class II	Same
Indication for use/ Intended use	With radiotherapy equipment (Medical Linac, CT-Sim), it is used for patient positioning before treatment and continuous monitoring of patients during treatment, and can also be used to track patients' breathing mode(including DIBH, EEBH, 4DCT three breathing modes), in order to implement image acquisition synchronized with breathing and radiation therapy.	The Catalyst system is intended for use in radiation therapy clinics to accurately set-up and position patients in a reproducible way prior to treatment, and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment and disables the treatment beam in case of large detected movements. The system can also track the patient's respiratory motion for supporting synchronized image acquisition or gated treatment delivery. The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostic imaging departments.	The Sentinel system is intended for use in radiation therapy clinics to accurately position patients in a reproducible way, prior to treatment and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment. The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostic imaging departments.	Same
Prescription or OTC	Prescription	Prescription	Prescription	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device**	**Remark**
Target population	External-beam radiation therapy patients	External-beam radiation therapy patients	External-beam radiation therapy patients	Same
Anatomical sites	No specific restrictions	No specific restrictions	No specific restrictions	Same
Where used	Hospital	Hospital	Hospital	Same
Energy used and/or delivered	Visible light (LED) Wavelength: 465nm	Visible light (LED) Wavelength: 405nm	Visible light (laser)	Similar
Human factors	Only qualified and trained personnel are allowed to run the system.	Only qualified and trained personnel are allowed to run the system. Usability validation tests performed in collaboration with hospitals.	Only qualified and trained personnel are allowed to run the system. Usability validation tests performed in collaboration with hospitals.	Same
Design	Optical triangulation measurement system using structured visible light pattern using LED light source and digital cameras.	Optical triangulation measurement system using structured visible light pattern using one LED light source and digital camera. Additional LED light sources for projecting visible light patterns.	Optical triangulation measurement system using structured visible light pattern using one LED light source and one digital camera.	Same
Main function modules	Patient positioning: Inter-session patient setup/positioning; Treatment (motion) monitoring: Monitor the patient's surface in real-time throughout the treatment session; Respiratory gating: Track respiratory movement.	cPosition: Fast and accurate patient positioning; cMotion: Motion detection during treatment delivery procedure; cRespiration: Respiratory motion monitoring.	cPosition: Fast and accurate patient positioning; cMotion: Motion detection during treatment delivery procedure.	Same
Power source	AC 100-240V, 47~63Hz	Not publicly available	Not publicly available	Different
Product structure	Advanced software, PC workstation, one or three 3D cameras and calibration tools.	Projector unit hardware and Windows based software	Scanner unit and c4D multi-application software	Similar Key components are all camera and software
Measurement accuracy	Measurement accuracy better than 1mm	Measurement accuracy better than 1mm	Measurement accuracy better than 1mm	Same

Comparison Elements	Subject Device	Predicate Device	Reference Device	Remark
Scan volume	ARSG-E1A: Not less than 1100 × 900×1000mm. ARSG-E3A: Not less than 1100 × 1100×1000mm.	Not publicly available	800×1300×700mm	Similar
Measurement reproducibility	No greater than 0.5mm	0.2mm	0.2mm	Similar
Respiratory gating accuracy	≤1mm	Within 1mm for rigid body	Within 1mm for rigid body	Same
Laser classification	Class I	Class II	Not publicly available	Different
Electrical safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	Same
Materials	No hazardous materials used, system not in direct contact with patients.	No hazardous materials used, system not in direct contact with patients.	No hazardous materials used, system not in direct contact with patients.	Same
Biocompatibility	Evaluated as per ISO 10993-1	N/A	N/A	Similar
Compatibility with the environment and other devices	EMC according to IEC 60601-1-2	EMC according to IEC 60601-1-2	EMC according to IEC 60601-1-2	Same
Sterility	N/A Not supplied sterile or intended to be sterilized by user	N/A	N/A	Same
Mechanical safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	Same
Chemical safety	N/A	N/A	N/A	Same
Thermal safety	N/A	N/A	N/A	Same
Radiation safety	N/A	N/A	N/A	Same

(7) Non-clinical studies and tests

Non-clinical tests were conducted to verify that the Klarity SGRT System (ARSG-E1A, ARSG-E3A) meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results also demonstrate that the device complies with the following standards and guidance:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

- IEC TS 60601-4-2, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-8, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 62471, Photobiological safety of lamps and lamp systems
- IEC 60825-1, Safety of laser products - Part 1: Equipment classification, and requirements
- The FDA "Guidance for Pre-Market Submissions and for Software Contained in Medical Devices- Guidance for Industry and Food and Drug Administration Staff issued 2023". The software documentation for this device was considered as Enhanced Documentation Level.
- The FDA "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions- Guidance for Industry and Food and Drug Administration Staff 2023.

Biocompatibility

The biocompatibility of this device have been evaluated and demonstrated conformance to the following standards:

- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Usability

Usability engineering study has been conducted and demonstrated conformance to the following standard and guidance:

- IEC 60601-1-6, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- The FDA "Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff February 2016"

Performance

In order to verify and assure the performance, function and quality of the product, we have conducted performance verification to verify that the product performance conforms to device specification, compare the performance with predicate/reference device and verify the compatibility with CT and linear accelerator. The corresponding test reports can be seen in:

- Performance test reports;
- Comparative test reports;

- Compatibility test reports with CT and Linear Accelerator.

Clinical testing

The clinical test is not applicable, there's no clinical data.

(8) Conclusion

Based on the above analysis and tests, it can be concluded that the Klarity SGRT System (ARSG-E1A, ARSG-E3A) is substantially equivalent to the predicate device Catalyst and the noted differences do not raise questions of safety and effectiveness.