Our United Corporation
% Mr. Qi Liu
Regulatory Affairs Engineer
Room 10301, 3rd Floor, Unit 1, Block 28, ShouChuang
International Business Center, No.66
Xi'an, Shaanxi 710018
CHINA

March 12, 2021

Re: K203250
Trade/Device Name: TaiChiC
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: Class II
Product Code: IWB
Dated: February 3, 2021
Received: February 10, 2021

Dear Mr. Qi Liu:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203250

Device Name
TaiChiC

Indications for Use *(Describe)*
The system is a teletherapy device intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions in the brain and head where radiation treatment is indicated.

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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Premarket Notification [510(k)] Summary
OUR UNITED CORPORATION
TaiChiC Rotating Gamma System

The following information is provided following the format of 21 CFR 807.92.

I. GENERAL INFORMATION

K203250

Submitter's Name: OUR UNITED CORPORATION
Room 10301, 3rd Floor, Unit 1, Block 28, Shou Chuang International Business Center, No.66 Fengcheng 12 Road, Xi'an Economic & Technological Development Zone, 710018, Shaanxi, China.

Contact Person: Qi Liu
Phone: +86 15389012257
Email: qi.liu@ourunited.com

Date Prepared: Oct. 30th 2020

II. DEVICE INFORMATION

Proprietary Name: TaiChiC

Common/Usual Name: Rotating Gamma System

Classification Name: Radionuclide radiation therapy system

Device Regulation: 21 CFR 892.5750

Regulatory Class: II

Product Code: IWB

III. PREDICATE DEVICE

Primary Device Akesis Galaxy RTx (K200050)

Classification Name: Radionuclide radiation therapy system

Device Regulation: 21 CFR 892.5750

Regulatory Class: II

Product Code:	IWB
Reference Device	TaiChiA Medical Linear Accelerator (K193207)
Classification Name:	Medical charged-particle radiation therapy system
Device Regulation:	21 CFR 892.5050
Regulatory Class:	II
Product Code:	IYE

IV. Device Description:

TaiChiC Rotating Gamma System has been designed to deliver radiation treatments in accordance with a prescribed plan. This system is a stereotactic radiotherapy equipment developed by applying the principle and mature technology of Cobalt-60 rotary focusing. It is suitable for brain and head lesions and tumors requiring radiotherapy, and provides image guided stereotactic radiosurgery and precision radiotherapy.

TaiChiC consists of a gantry with a slip ring, a focusing gamma ray treatment head, image guidance subsystem, couch, power supply and electrical cabinet, main cover and treatment bore etc. TaiChiC combines gamma beam stereotactic radiation therapy technology with contemporary advanced image guidance technology (IGRT) to provide image guided stereotactic radiotherapy and precision radiotherapy.

V. Intended Use:

The system is a teletherapy device intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions in the brain and head where radiation treatment is indicated.

VI. Indications for Use:

The system is a teletherapy device intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions in the brain and head where radiation treatment is indicated.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

TaiChiC and predicate Akesis Galaxy RTx are both Radionuclide radiation therapy system, falling within 21 CFR 892.5750, product code IWB. The proposed TaiChiC is comparable to the predicate device with respect to the intended use, indications for use, technological characteristics and similar performance specifications.

The TaiChiC is also appropriately comparable to another device, TaiChiA Medical Linear Accelerator, cleared under 510(k) K193207. TaiChiA Medical Linear Accelerator is classified as a Medical charged-particle radiation therapy system, falling within 21 CFR 892.5050, product code IYE. This reference device is included as it is similar to TaiChiC with respect to indications for use, imaging techniques, gantry rotation, patient immobilization, couch and other features.

With regards to technological characteristics, the TaiChiC Rotating Gamma System, the predicate device and the reference device all have similar features and components. TaiChiC and the predicate device have same intended use, and both fall within the broader scope of the reference device. TaiChiC and Akesis Galaxy RTx both utilize Cobalt-60 radiation source to generate the treatment beam. All three systems have patient supporting system (couch) to support and position the patient during the treatment. All three systems have control consoles and interface software to control and monitor the systems. All three systems protect the operator and the general public from the radiation from the machine.

The main differences between TaiChiC and the predicate device include the number of sources used, the image guidance and the number of the collimator sets.

Comparing with the predicate device with 30 radioactive sources, TaiChiC has only 18 sources but with higher activities to provide a comparable dose rate at the focal spot, which is appropriate for the intended use.

The CBCT and kV-kV imaging techniques used in TaiChiC are similar as those in the reference device, while the predicate device does not provide this technique.

TaiChiC provides 7 sets of collimators with beam diameter at the focal spot of 6mm, 9mm, 12mm, 16mm, 20mm, 25mm and 35mm. While the predicate device provides 4 sets of collimators Φ 4 mm， Φ 8 mm, Φ 14 mm and Φ 18 mm. The first four sets of TaiChiC collimators (Φ 6mm, φ9mm, φ12mm, φ16mm) are comparable to those of the predicate device and all the collimators of TaiChiC fall within the broad beam collimating sizes of the reference device.

The above differences among the proposed device, the predicate and the reference device do not raise any safety and effectiveness issues.

The comparisons between the proposed TaiChiC Rotating Gamma System and the predicate device Akesis Galaxy RTx, the reference device TaiChiA Medical Linear Accelerator are provided in the table below.

NO.	Feature	New Device	Predicate Device (K200050)	Reference Device (K193207)	Analysis of Differences
1	Product Name	OUR TaiChiC Rotating Gamma System.	Akesis Galaxy RTx	OUR TaiChiA Medical Linear Accelerator	——
2	Intended Use	TaiChiC is a teletherapy device intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions in the brain and head where radiation treatment is indicated.	The Akesis Galaxy RTx system is a teletherapy device intended for the stereotactic irradiation of head structures.	TaiChiA is a Medical Linear Accelerator, intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.	The new device has same intended use as the Predicate device, and has same intended use as the Reference device for treatment of lesions in the brain and head
3	Indications for Use	ThiChiC is a teletherapy device intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions in the brain, and head, where radiation treatment is indicated.	The Akesis Galaxy RTx system is a teletherapy device intended for the stereotactic irradiation of head structures.	TaiChiA, is a Medical Linear Accelerator, intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.	The new device has same intended use as the Predicate device, and has same intended use as the Reference device for treatment of lesions in the brain and head
4	Radiation source	Cobalt 60	Cobalt 60	6MV X-ray	The new device radiation source is the same with the Predicate Device
5	Initial Total activity	22860 Ci ±5%	6000 Ci ±10%	Treatment beam 6 MV nominal photon beam energy.	The new device total cobalt-60 activity at loading is higher than the Predicate Device, but the dose rate at the focal spot is at the same level.
6	Number of radiation sources	18	30	Treatment beam 6 MV nominal photon beam energy.	The radioactive sources of the new device have higher activities, and so less radiation sources are needed compared with Predicate device

7	Initial Dose rate at the focal spot	≥3.5Gy / min	> 3.0Gy / min	Up to 14 Gy / min	Radiation dose rate at focal spot at loading for the new device is very comparable to the Predicate device which is appropriate for the intended use.
8	Number of collimator sizes (and nominal aperture size)	7: φ6mm, φ9mm, φ12mm, φ16mm, φ20mm, φ25mm and φ35mm	4: φ4 mm，φ8 mm，φ14 mm, φ18 mm	NA	The new device utilizes 7 sets of collimator cones to collimate the Gamma rays, the collimator sizes of the new device collimator sizes (φ6mm, φ9mm, φ12mm, φ16mm) are similar with the Predicate device.
9	Radiologic accuracy	<0.5mm	<0.5mm	≤1.0mm	The new device radiologic accuracy is the same as the Predicate device
10	Patient Couch	Yes	Yes	Yes	All systems have a patient couch to support patient during treatment.
11	Imaging techniques	CBCT、kV-kV	NA	CBCT、kV-kV	The new device imaging techniques is the same with the Reference device.
12	Patient immobilization method	The Encompass™ SRS Immobilization System	Stereotactic Head Frame and Positioning System	The Encompass™ SRS Immobilization System	The new device lesion localization falls within the range of the predicate, and same as the reference device.

V. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence:

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and electromagnetic compatibility (EMC) testing were conducted on this medical device. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Bench Test
Successful testing was performed in accordance with following standards:

IEC 60601-2-11: 2013, particular requirements for the basic safety and essential performance of gamma beam therapy equipment

IEC60601-1-3:2013, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

IEC60601-2-68:2014, 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

IEC61217:2011, Radiotherapy equipment - Coordinates, movements and scales

IEC62274 :2005, Medical electrical equipment - Safety of radiotherapy record and verify systems

IEC62366-1:2015, Medical devices - Part 1: Application of usability engineering to medical devices

IEC60601-1-6:2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

RT2:2017 Radiation therapy readiness check

ISO 15223-1: 2016, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements

ISO10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Hardware and Software Verification and Validation Testing
Hardware and software verification and validation process were conducted according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, ISO 14971 Risk Management Standard and the other FDA recognized consensus standards.

Test results showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly. Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern.

Animal or clinical test
Not applicable for TaiChiC

Summary
The verification and validation testing demonstrated that TaiChiC has met its specifications, demonstrated substantially equivalent performance to the predicate and met its intended use.

VI. CONCLUSIONS

The TaiChiC has the same intended use, indications for use, fundamental scientific technology as the predicate device.

The difference among TaiChiC and predicate does not raise any new safety or effectiveness issues. The differences are substantial equivalent to the reference device

The Verification and Validation demonstrates that the device is as safe and effective as the predicate device.

Based on the comparison and analysis above, OUR therefore believes that TaiChiC is substantially equivalent to the predicate device.