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

November 2, 2021

Re: K210921
Trade/Device Name: TaiChiB
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE, IWB
Dated: March 26, 2021
Received: March 29, 2021

Dear Ms. 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, PhD.
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)*
K210921

Device Name
TaiChiB Digital Radiotherapy System

Indications for Use *(Describe)*
TaiChiB Digital Radiotherapy System is a teletherapy device equipped with two radiation beam delivery units within an enclosed gantry.
(1) The electron linear accelerator producing 6MV photon beam is indicated to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
(2) The rotating focused gamma beam emitting unit with multiple Cobalt-60 sources is indicated 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
TaiChiB Digital Radiotherapy System

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

I. GENERAL INFORMATION

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
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Email: qi.liu@ourunited.com

Date Prepared: Sep. 27^{thth}2021

II. DEVICE INFORMATION

Proprietary Name: TaiChiB

Common/Usual Name: TaiChiB Digital Radiotherapy System

Classification Name: Medical charged-particle radiation therapy system
Radionuclide radiation therapy system

Device Regulation: 21 CFR 892.5050; 21 CFR 892.5750

Regulatory Class: II

Product Code: IYE; IWB

III. PREDICATE DEVICE

Primary 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
Reference Device	TaiChiC Rotating Gamma System (K203250)
Classification Name:	Radionuclide radiation therapy system
Device Regulation:	21 CFR 892.5750
Regulatory Class:	II
Product Code:	IWB

IV. Device Description:

TaiChiB Digital Radiotherapy System integrates medical linear accelerator technology and rotating gamma technology for precision radiotherapy and stereotactic radiosurgery.

TaiChiB contains a gantry with a slip ring, 6 MV X-ray Beam Generation Module (BGM), Beam Shaping Module (BSM), Rotating Gamma Subsystem (RGS), Image Guidance System (IGS), Patient Support System (PSS), Treatment Control System (TCS).

V. Intended Use:

TaiChiB Digital Radiotherapy System is a teletherapy device equipped with two radiation beam delivery units within an enclosed gantry.
(1) The electron linear accelerator producing 6MV photon beam is indicated to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
(2) The rotating focused gamma beam emitting unit with multiple Cobalt-60 sources is indicated 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:

TaiChiB Digital Radiotherapy System is a teletherapy device equipped with two radiation beam delivery units within an enclosed gantry.
(1) The electron linear accelerator producing 6MV photon beam is indicated to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
(2) The rotating focused gamma beam emitting unit with multiple Cobalt-60 sources is indicated 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 the Technological Characteristics with the Predicate Device

TaiChiB is a comprehensive radiotherapy system including a medical linear accelerator system and a rotating gamma focusing system (RGS). TaiChiB integrates the rotating gamma focusing system from TaiChiC Rotating Gamma System(K203250) into the TaiChiA Medical Linear Accelerator System (K193207). There are ONLY two treatment modes in TaiChiB, Linac mode and Gamma mode, and these two modes are activated independently through a hardwired interlock, i.e. when one mode is activated another is prohibited. Beams from two subsystems are delivered independently. TaiChiB system enables the accelerator-based radiation therapy and RGS-based stereotactic radiosurgery to be completed in one device and one treatment room.

TaiChiA (K193207) from OUR UNITED CORPORATION is included as the primary predicate device, because TaiChiB and TaiChiA have same intended use, indications for use and same medical linear accelerator performance specifications for Linac mode. TaiChiB is designed on the same platform as TaiChiA with only adding the gamma focusing subsystem on the gantry. It keeps the same system architecture design as TaiChiA including the gantry, the linear accelerator, the couch, the image guidance system. The medical linear accelerator system used in both devices have the same FFF beam with energy of 6MV, Maximum dose rate of up to 1400cCy/min, and Maximum treatment field of 40×40cm.

Since TaiChiB has an extra rotating gamma focusing system compared with the predicate device TaiChiA Medical Linear Accelerator System(K193207), TaiChiC Rotating Gamma System (K203250) from OUR UNITED CORPORATION is included as the reference device, because the rotating gamma focusing system from TaiChiB is the same as rotating gamma focusing system used in TaiChiC for Gamma mode. They have same intended use, indications for use, structural design, and dosimetry specifications. The rotating gamma focusing system used in both devices are teletherapy devices intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions in the brain and head where radiation is indicated. The two rotating gamma focusing systems utilize rotational circular cone to collimate and deliver the treatment. Both rotating gamma focusing systems have the same initial dose rate as $\geqslant$3.5Gy/min and radiological accuracy$<$0.5mm at the focal point.

The above-mentioned differences between TaiChiB and TaiChiA have been verified and validated. The verification and validation test results proved that these differences will not affect the safety and effectiveness of TaiChiB in treating patients. The TaiChiB system is as safe and effective as the predicate device and reference device.

Detailed comparisons among TaiChiB, TaiChiA (the predicate device), and TaiChiC (the reference device) are provided in the following tables respectively.

Detailed Comparisons of TaiChiB with TaiChiA (Predicate Device) and TaiChiC (Reference Device)

NO.	Feature	New Device (K210921)	Predicate Device (K193207)	Reference Device (K203250)	Analysis of Differences
General Information					
1.	Product Name	TaiChiB Digital Radiotherapy System	TaiChiA Medical Linear Accelerator	TaiChiC Rotating Gamma System.	____
2.	Indications for Use	TaiChiB Digital Radiotherapy System is a teletherapy device equipped with two radiation beam delivery units within an enclosed gantry. (1) The electron linear accelerator producing 6MV photon beam is indicated to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated. (2) The rotating focused gamma beam emitting unit with multiple Cobalt-60 sources is indicated to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions in the brain and head where radiation treatment is indicated.	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.	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.	When use linac treatment in the body, the Indications for Use is as same as the Predicate device due to the functionality, performance and workflow is as same as the Predicate device (K193207). When use Rotating Gamma System treatment in the brain and head, the Indications for Use is as same as the reference device due to the functionality, performance and workflow is as same as the reference device (K203250).
3.	Treatment delivery techniques	3DCRT, IMRT, VMAT, stereotactic radiosurgery,	3DCRT, IMRT, VMAT	Stereotactic radiosurgery, precision radiotherapy	3DCRT, IMRT, VMAT are same as the predicate device,

		Precision radiotherapy			Stereotactic radiosurgery and precision radiotherapy are same as the reference device for head.
4.	Radiation source	Cobalt 60	NA	Cobalt 60	Same as the reference device.
5.	Quantity of radiation sources	18	NA	18	Same as the reference device.
6.	Distance from source to focal spot (cm)	75	NA	75	Same as the reference device.
7.	Initial Dose rate at the focal spot[1]	≥3.5Gy / min	NA	≥3.5Gy / min	Same as the reference device.
8.	Quantity of collimator and nominal aperture size	7: φ6mm, φ9mm, φ12mm, φ16mm, φ20mm, φ25mm and φ35mm	NA	7: φ6mm, φ9mm, φ12mm, φ16mm, φ20mm, φ25mm and φ35mm	Same as the reference device.
9.	Collimator selection	Automatically	NA	Automatically	Same as the reference device.
10.	Radiologic accuracy	<0.5mm	NA	<0.5mm	Same as the reference device.
11.	Beam energy (MV)	6MV, FFF	6MV, FFF	NA	Same as the Predicate device.
12.	Maximum dose rate (cGy/min)	Up to 1400	Up to 1400	NA	Same as the Predicate device.
13.	Maximum treatment field (cm)	40×40	40×40	NA	Same as the Predicate device.
14.	Dmax (cm)	1.5±0.2 cm	1.5±0.2 cm	NA	Same as the Predicate device.
15.	Percentage dose at 10 cm depth (%)	65.0±2.0	65.0±2.0	NA	Same as the Predicate device.
16.	Source to axis distance(cm)	100	100	NA	Same as the Predicate device
17.	Collimator rotation range(degrees)	± 90	± 90	NA	Same as the Predicate device.
18.	Number of MLC leaves	120	120	NA	Same as the Predicate device.

19.	Leaf resolution at isoplane(cm)	0.5 and 1	0.5 and 1	NA	Same as the Predicate device.
20.	Average leaf transmission (%)	≤1.0	≤1.0	NA	Same as the Predicate device.
21.	Gantry rotation range (degrees)	No limit（continuous rotation）	No limit（continuous rotation）	No limit（continuous rotation）	Same design with different load installed as the Predicate device and reference device.
22.	Isocenter height relative to the floor (cm)	95	95	95	Same design with different load installed as the Predicate device and reference device.
23.	Bore Diameter (cm)	95	95	95	Same design with different load installed as the Predicate device and reference device.
24.	Gantry maximum rotational speed (RPM)	Up to 1.0	Up to 1.0	Up to 1.0	Same design with different load installed as the Predicate device and reference device.
25.	Shift positioning accuracy (cm)	≤0.05	≤0.05	≤0.05	Same design as the Predicate device and reference device.
26.	Degrees of freedom	3	3	3	Same design as the Predicate device and reference device.
27.	Lateral travel range (cm)	±15.0	±15.0	±15.0	Same design as the Predicate device and reference device.
28.	Vertical travel range (cm)	-28.0 to 5.0	-28.0 to 10.0	-28.0 to 5.0	Similar as the predicate device, same as the reference device. This difference does not affect the safety and effectiveness of the device. Mechanical hardware design of three products are same. The vertical travel range of predicate device, reference device and new device are set by an electrical limit switch and software.

					The new device and reference device have same electrical limit switch installation and software parameters setting of vertical travel range, so the Vertical travel range are same. The new device and predicate device have different electrical limit switch installation and software parameters setting of vertical travel range, so the Vertical travel range are different.
29.	Longitudinal travel range (cm)	180.0	180.0	180.0	Same design as the Predicate device and reference device.
30.	Imaging beam	kV	kV	kV	Same design as the Predicate device and reference device.
31.	Imaging techniques	CBCT, kV/kV	CBCT, kV/kV	CBCT, kV/kV	Same design as the Predicate device and reference device.
32.	Imaging field of view (cm)	ϕ25.0 for head scan ϕ44.5 for body scan	ϕ25.0 for head scan ϕ44.5 for body scan	ϕ25.0 for head scan	same as the predicate device, same as the reference device of head scan. Hardware design of three products is same. The functionality of imaging field of view is configurable. The new device and predicate device have same configuration of imaging field of view. The new device and reference device have different software configuration of imaging field of view due to the reference device is used on brain and head.

33.	CBCT acquisition Mode (pixels/degrees)	512×512 reconstruction matrix/ 200（head） or 360（body）	512×512 reconstruction matrix/ 200（head） or 360（body）	512×512 reconstruction matrix/ 200（head）	same as the predicate device, same as the reference device at head

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: 2012 standard for safety and the IEC 60601-1-2:2014 standard for EMC.

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

IEC60976:2007, Medical electrical equipment - Medical electron accelerators - Functional performance characteristics

IEC 60601-2-1: 2014, Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

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

ISO10993-1:2018, 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 TaiChiB conforms to applicable requirements specifications and assures 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 TaiChiB

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

VI. CONCLUSIONS

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

The differences among TaiChiB and predicate have been verified and validated and do not raise any new safety or effectiveness issues.

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

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