Our United Corporation
℅ Qi Liu
Regulatory Affairs Engineer
3rd Floor, Unit 1, Block 28
ShouChuang International Business Center, NO.66
Xi'an, Shaan xi 710018
CHINA

August 7, 2020

Re: K193207
Trade/Device Name: TaiChiA
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: July 5, 2020
Received: July 10, 2020

Dear 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193207

Device Name
TaiChiA

Indications for Use *(Describe)*

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.

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
TaiChiA Medical Linear Accelerator

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

K193207

I.GENERAL INFORMATION

Date Prepared:	July 5th 2020
Submitter's Name:	OUR UNITED CORPORATION 3rd Floor, Unit 1, Block 28, ShouChuang International Business Center, No.66, Fengcheng 12 Road, Weiyang District, Xi'an City, Shaanxi Province, China.
Contact Person:	Qi Liu Phone: +86 15389012257 Email: qi.liu@ourunited.com
II.DEVICE INFORMATION **Proprietary Name:**	TaiChiA
Classification Name:	Medical charged-particle radiation therapy system
Device Regulation:	21 CFR 892.5050
Device Class:	Class II
Product Code:	IYE
Common/Usual Name:	Medical Linear Accelerator
III.PREDICATE DEVICE	Varian Medical Systems Halcyon (K181032)
Reference Device	TrueBeam, TrueBeam STx, and Edge Radiotherapy Delivery System (K171733)
IV. Device Description:	TaiChiA Medical Linear Accelerator, has been designed to deliver radiation treatment in accordance with a prescribed plan. This system utilizes kV image guidance technology (IGRT) to deliver photon based radiation therapy treatments, using an integrated rotating linear accelerator system.

	TaiChiA is a single energy medical linear accelerator designed to deliver Image Guided Radiation Therapy and Radiosurgery, using 3DCRT, IMRT and VMAT techniques. It consists of the accelerator and patient support within a radiation shielded treatment room and a control console in the control room.
V. Intended Use:	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.
VI. Indications for Use:	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.

VII. COMPARISION WITH THE PREDICATE DEVICE

The Halcyon system (K181032) from Varian Medical Systems, Inc. (Palo Alto, CA) is selected as the primary predicate device of the TaiChiA system from OUR United Corporation (Xi'an, China) because of their similarities. Both devices have the same general intended use and indications for use, i.e., provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated. The two systems have similar major components and comparable specifications that include beam energy, Dmax, depth dose at 10cm, symmetry, off axis intensity, dose output and constancy, collimator rotation, target to gantry axis distance, bore diameter, radiation isocenter size, maximum leaf over travel, leaf interdigitating, leaf end position accuracy, low MLC leaf leakage, shift positioning accuracy and degrees of freedom.

The two systems have few different specifications on beam collimation, maximum dose rate, imaging system, gantry rotation and couch. Regarding beam collimation, TaiChiA is equipped with a single layer MLC with a maximum leaf speed of 2.5cm/s and maximum field size of 40cm x 40cm, while Halcyon has a double layer MLC with maximum leaf speed of 5.0cm/s and maximum field size of 28cm x 28cm. Halcyon supports a faster MLC leaf speed but has a smaller treatment field size. Compared to Halcyon, TaiChiA has a higher maximum dose rate (1400cGy/min vs. 800cGy/min) which can improve treatment efficiency. Regarding gantry rotations, based on slip-ring technology, TaiChiA can rotate the gantry continuously, while Halcyon is limited to +/- 185 degrees from the nominal angle with a state of zero degree, but has a faster maximum rotation speed. While both systems have a treatment couch weight specification which supports 95% of the patient population, Halcyon has a higher supported maximum weight limit. Due to the differences of isocenter height and gantry structure, TaiChiA has different couch travel range than Halcyon, but both systems meet the clinical coverage requirements of all standard treatment types.

As TaiChiA has some appreciable differences with Halcyon regarding the maximum dose rate, the beam collimation system, and the imaging system, the Varian TrueBeam system (K171733) is selected as the reference device for comparisons with TaiChiA. The TrueBeam system just like TaiChiA has an identical intended use, a 6MV FFF beam with maximum dose rate of 1400cGy/min, and is equipped with a single layer MLC system with 2.5cm/s maximum leaf speed and a maximum field size of 40cm x 40cm, and kV imaging capabilities.

The above-mentioned differences between TaiChiA and Halcyon have been verified and validated. It is demonstrated that these differences do not affect the TaiChiA's safety and effectiveness for patient treatment. The TaiChiA system is as safe and effective as the predicate device.

Detailed comparisons of TaiChiA with Halcyon (the predicate device) and TrueBeam (the reference device) are provided in the following tables, respectively.

Comparisons of TaiChiA with Halcyon (Predicate Device)

NO.	Attribute/Feature	Predicate Device Varian Halcyon (K181032)	Proposed Device TaiChiA Medical Linear Accelerator
General Information			
1	Intended Use	The Halcyon radiotherapy delivery system is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body 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.
2	Indications for Use	Halcyon is indicated for the delivery of stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated for adults and pediatric patients.	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.
Beam Specification			
3	Beam energy (MV)	6MV, FFF	6MV, FFF
4	Maximum dose rate (cGy/min)	Up to 800	Up to 1400
5	Maximum treatment field (cm)	28×28	40×40
6	Dmax (cm)	1.3±0.2	1.5±0.2
7	Percentage dose at 10 cm depth (%)	63.0 ± 1.0	65.0 ± 2.0
8	Off axis intensity (%)	79.0 ± 2.0	76.0 ± 2.0
9	Symmetry (%)	≤ 2.0	≤ 3.0
Dosimetry Specifications			
10	Dose output vs. Total MU requested	1.0% or 1.0 MU whichever is greater	2%
11	Dose output constancy vs gantry angle (%)	± 1.0	± 1.0
Geometric Specifications			
12	Gantry rotation range (degrees)	± 185	No limit（continuous rotation）

13	Collimator rotation range (degrees)	± 90	± 90
14	Source to axis distance (cm)	100	100
15	Isocenter height relative to the floor (cm)	110	95
16	Bore Diameter (cm)	100	95
17	Radiation isocenter size (mm)	≤ 0.90	≤ 1.0
18	Gantry maximum rotational speed (RPM)	Up to 4.0	Up to 1.0
19	Collimator maximum rotation speed (RPM)	Up to 2.5	Up to 1.0
Beam Shaping Specifications			
20	Multi-Leaf Collimator (MLC)	Two layers opposed leaf banks	Single layer opposed leaf banks
21	Maximum leaf speed (cm/sec)	Up to 5.0	Up to 2.5
22	Number of MLC leaves	114 (in two layers)	120
23	Leaf resolution at isoplane (cm)	1.0	0.5 and 1.0
24	Maximum leaf over travel (cm)	14.0	16.0
25	Leaf interdigitating	Yes	Yes
26	Leaf end position accuracy (cm)	± 0.1	± 0.1
27	Average leaf transmission (%)	≤ 0.01	≤ 1.0
Couch Specifications			
28	Weight limit with IGRT couch top (kg)	228	135
29	Shift positioning accuracy (cm)	≤ 0.05	≤0.05
30	Degrees of freedom	3	3
31	Lateral travel range (cm)	± 20.8	± 15.0
32	Vertical travel range (cm)	-47.5 to 0.0	-28.0 to 10.0
33	Longitudinal travel range (cm)	165.5	180.0
Imaging Specifications			
34	Imaging beam	MV	kV

35	Imaging field of view (cm)	28.0 × 28.0	ϕ25.0 for head scan ϕ44.5 for body scan
36	Image and treatment coincidence (cm)	≤ 0.1	≤0.1
37	CBCT acquisition mode (pixels/degrees)	256 x 256 reconstruction matrix / 200	512×512 reconstruction matrix/ 200（head） or 360 （body）
38	Dose per orthogonality imaging acquisition	2 or 4MU (cGy) MV-MV	<0.1cGy kV-kV
39	Dose per CBCT acquisition	5 or 10 (cGy)	<1.0cGy
Treatment Delivery and Imaging Acquisition Specifications			
40	Imaging techniques	MV CBCT (3D) or MV/MV (2D)	kV CBCT (3D) or kV/kV (2D)
41	Treatment delivery techniques	3D, 3DCRT Field in Field, IMRT/IMRS, RapidArc and VMAT	3DCRT, IMRT, VMAT

Comparisons of TaiChiA with TrueBeam (Reference device)

NO.	Attribute/Feature	Reference Device TrueBeam (K171733)	Proposed Device TaiChiA Medical Linear Accelerator
Dose Rate, Field size, MLC and Gantry, Collimator rotation speed			
1	Beam energy (MV)	6/8/10/15/18/20MV with FF 6/10MV with FFF 6MV with FFF is one of TrueBeam's beam energy	6MV with FFF
2	Maximum dose rate (cGy/min)	Up to 1400 with FFF at 6MV beam	Up to 1400 with FFF at 6MV beam
3	Dose Monitoring System Proportionality	±1%	2%
4	Maximum treatment field (cm)	40×40	40×40
5	Multi-Leaf Collimator (MLC)	Single layer opposed leaf banks	Single layer opposed leaf banks
6	Maximum leaf speed (cm/sec)	Up to 2.5	Up to 2.5
7	Leaf resolution at isoplane (cm)	0.5 and 1.0	0.5 and 1.0
8	Number of MLC leaves	120	120
9	Average leaf transmission (%)	≤ 2.0	≤ 1.0
10	Gantry maximum	Up to 1.0	Up to 1.0

	rotational speed (RPM)		
11	Collimator maximum rotation speed (RPM)	Up to 1.0	Up to 1.0
Imaging Specifications			
12	Imaging techniques	kV CBCT or kV/kV	kV CBCT or kV/kV
13	Imaging beam	kV	kV
14	Imaging field of view (cm)	ϕ25.0 for head scan ϕ46.0 for body scan	ϕ25.0 for head scan ϕ44.5 for body scan
15	Imaging length(cm)	17.0 for head scan 15.5 for body scan	17.0 for head scan 19.0 for body scan
16	CBCT acquisition mode (pixels/degrees)	512×512 reconstruction matrix/ 200 （head） or 360 （body）	512×512 reconstruction matrix/ 200 （head） or 360 （body）
17	Dose per orthogonality imaging acquisition	<0.1cGy kV-kV	<0.1cGy kV-kV
18	Dose per CBCT acquisition	<1.4cGy	<1.0cGy

VIII. 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 60601-1Medical Electrical Equipment - Part I General requirements for basic safety and essential performance for the safety and the IEC 60601-1-2 Medical electrical equipment Part 1-2 General requirements for basic safety and essential performance - Collateral standard Electromagnetic compatibility-Requirements and tests for EMC.

Bench Test
Successful testings were performed in accordance with following standards:

IEC60601-2-1:2005, 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

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

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

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 TaiChiA

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

IX. CONCLUSIONS
The TaiChiA has the same intended use, fundamental scientific technology and principles of operation as the predicate device.

The differences between TaiChiA and predicate device do not raise any new safety or effectiveness issues. The differences are substantial equivalent to the reference device.

The Verification and Validation demonstrate that the device is as safe and effective as the predicate. OUR therefore believes that TaiChiA is substantially equivalent to the predicate device.