Manteia Technologies Co., Ltd.
% Chao Fang
RA manager
1903-1904, B Tower, Zijin Plaza
No.1811 Huandao East Road
Xiamen, Fujian 361001
CHINA

August 15, 2023

Re: K223834
Trade/Device Name: AccuCheck
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE

Dear Chao Fang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 20, 2023. Specifically, FDA is updating this SE Letter with the correct contact as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lora Weidner, OHT8: Office of Radiological Health, 240-402-6424, lora.weidner@fda.hhs.gov.

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

Manteia Technologies Co., Ltd.
℅ Yingkai Lin
RA Manager
1903-1904, B Tower, Zijin Plaza
No.1811 Huandao East Road
Xiamen, Fujian 361001
CHINA

July 20, 2023

Re: K223834
Trade/Device Name: AccuCheck
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: June 22, 2023
Received: June 22, 2023

Dear Yingkai Lin:

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
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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)*
K223834

Device Name
AccuCheck

Indications for Use *(Describe)*
AccuCheck is a quality assurance software used for data transfer integrity check, secondary dose calculation with Monte Carlo algorithm, and treatment plan verification in radiotherapy. AccuCheck also provides independent dose verification based on LINAC delivery log after radiotherapy plan execution.

AccuCheck is not a treatment planning system or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance purposes.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The following information is provided as required by 21 CFR 807.92.

The assign 510(k) Number: K223834

1. SUBMITTER

Manteia Technologies Co., Ltd.

1903-1904, B Tower, Zijin Plaza, No.1811 Huandao East Road, Xiamen,, China

Establishment Registration Number: 3016686005

Contact Person: Chao Fang

Position: RA&QA Manager

Email: fangchao@manteiatech.com

Date of Preparation: July 20, 2023

2. Identification of Proposed Device

Device/Trade Name: AccuCheck

Common Name: Radiotherapy Plan Quality Assurance System

Regulatory Information

Classification Name: accelerator, linear, medical

Classification: II

Product Code: IYE

Regulation Number: 21CFR 892.5050

Review Panel: Radiology

3. PREDICATE DEVICE

Predicate Device: Mobius 3D v4.0 (K203669)

Reference Device: INTDose (K213137)

4. DEVICE DESCRIPTION

AccuCheck is a quality assurance software used for data transfer integrity check, secondary dose calculation with Monte Carlo algorithm, and treatment plan verification in radiotherapy. AccuCheck also provides independent dose verification based on LINAC delivery log after radiotherapy plan execution. AccuCheck is not a treatment planning system or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance purposes.

AccuCheck performs using the TPS Check module to check related parameters in the radiotherapy plan to determine if the plan is executable by the linear accelerator(LINAC).

AccuCheck also performs using the Dose Check module to conduct dose calculation verification for radiation treatment plans before radiotherapy by doing an independent calculation of radiation dose using Monte Carlo algorithm. Radiation dose is initially calculated by a Treatment Planning System (TPS).

AccuCheck performs using the Transfer Check module to verify the integrity of the treatment plan transmitted from TPS to the LINAC to check if errors occur during the transmission.

AccuCheck performs dose delivery quality assurance for radiation treatment plans by using the measured data recorded in a LINAC's delivery log files to reconstruct executed plan and calculate delivered dose. This is achieved through the software module of the Subject Device called Pre-treatment Check and Treatment Check. The difference lies in the usage scenario, where Pre-treatment Check processes the logs of the first execution of the treatment plan in LINAC without a patient actually being treated, while treatment check processes the logs of the second and subsequent execution of the treatment plan in LINAC with a patient actually being treated. AccuCheck cannot be used for log verification, but rather for dose calculation based on logs such as LINAC delivery log data. The reconstruct of the executed plan and calculation of the delivered dose from delivery logs on LINAC machines, including Varian LINAC and Elekta LINAC, are supported by AccuCheck.

The product provides with multiple tools to assist the analysis, including dose volume histogram, Gamma analysis, target coverage, Gamma passing rate of each ROI, dose statistics and clinical targets evaluation.

5. INDICATIONS FOR USE

AccuCheck is a quality assurance software used for data transfer integrity check, secondary dose calculation with Monte Carlo algorithm, and treatment plan verification in radiotherapy. AccuCheck also provides independent dose verification based on LINAC delivery log after radiotherapy plan execution.

AccuCheck is not a treatment planning system or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance purposes.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

AccuCheck designed the corresponding functional modules considering the timeline of radiotherapy treatment. AccuCheck verified the feasibility and dose accuracy of the treatment plan before implementation. After execution, AccuCheck verified the consistency of data transmission and read the accelerator execution log to restore the treatment plan.

The primary technical feature of AccuCheck and its predicate device is to check the information of the plan files according to relative parameters to ensure the quality of the treatment plan. The verification of dose is an important part of ensuring the quality of treatment plan. When verifying the dose of the treatment plan, AccuCheck and its predicate device are used to perform a secondary dose calculation on the read or imported file and compare with the original plan dose, and present the results in various ways. The technological characteristics are believed to be substantially equivalent to the predicate device. The following comparison table "Device Comparison Table" provides a detailed comparison.

Device Comparison Table

Comparison item	Subject Device	Predicate Device Mobius 3D (K203669)	Reference Device INTDose (K213137)
Regulatory Information			
Indication for use	AccuCheck is a quality assurance software used for data transfer integrity check, secondary dose calculation with Monte Carlo algorithm, and treatment plan verification in radiotherapy. AccuCheck also provides independent dose verification based on LINAC delivery log after radiotherapy plan execution. AccuCheck is not a treatment planning system or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance purposes.	Mobius3D software is used for quality assurance, treatment plan verification, and patient alignment and anatomy analysis in radiation therapy. It calculates radiation dose three-dimensionally in a representation of a patient or a phantom. The calculation is based on read-in treatment plans that are initially calculated by a treatment planning system and may additionally be based on external measurements of radiation fields from other sources such as linac delivery log data. Patient alignment and anatomy analysis is	INTDose is a software product intended to support the radiation therapy treatment planning process by providing independent dose verification through Monte Carlo simulation. INTDose is not a treatment planning system or a radiation delivery device and should only be used by trained radiation oncology personnel as a quality assurance tool.

		based on read-in treatment planning images (such as computed tomography) and read-in daily treatment images (such as registered cone beam computed tomography). Mobius3D is not a treatment planning system. It is only to be used by trained radiation oncology personnel as a quality assurance tool.	
Independent Software	Yes	Yes	Yes
Product Code	IYE	IYE	IYE
Intended users	Trained radiation oncology personnel	Trained radiation oncology personnel	Trained radiation oncology personnel
Regulation No.	21 CFR 892.5050	21 CFR 892.5050	21 CFR 892.5050
Patient management features			
Displaying Patient and plan list	Yes	Yes	Yes
Displaying of Plan Check Results	Yes	Yes	Yes
DICOM RT	Yes (The device supports CT/ CBCT/ MR/ RTStruct/ RTPlan,/ RTDose)	Yes (The device supports CT/ CBCT/ RTStruct/ RTPlan,/ RTDose)	Yes (The device supports CT/ CBCT/ RTStruct/ RTPlan,/ RTDose)
Plan parameters checking features			
Supported treatment techniques	3D-CRT, IMRT, VMAT, SRS, SBRT	3D-CRT, IMRT, VMAT, SRS, SBRT, Brachythreaphy	TomoTherapy®, 3D-CRT, IMRT, VMAT
Displaying of inspection results	Yes	Yes	Yes
Dose verification features based on imported plan			
Supported treatment techniques	3D-CRT, IMRT, VMAT, SRS, SBRT	3D-CRT, IMRT, VMAT, Brachythreaphy	TomoTherapy®, 3D-CRT, IMRT, VMAT
DICOM data supported by dose calculation	CT/CBCT/MR, RTDose, RTStructures, RTPlan)	CT/CBCT, RTDose, RTStructures, RTPlan	CT/CBCT, RTDose, RTStructures, RTPlan

Beam type	Photon	Photon, Electron	Photon
Dose calculation algorithm	Monte Carlo algorithm	CCC/S algorithm for photo, PBRA algorithm for electron	Monte Carlo algorithm
Dose comparison	Yes	Yes	Yes
Displaying of inspection results	Yes	Yes	Yes
Plan transmission verification features			
Supported treatment techniques	3D-CRT, IMRT, VMAT, SRS, SBRT	3D-CRT, IMRT, VMAT, SRS, SBRT, Brachythreaphy	TomoTherapy®, 3D-CRT, IMRT, VMAT
Consistency check on transferred plans	Yes	Yes	No
Displaying of check results	Yes	Yes	N/A
Dose verification features based on accelerators' log			
LINAC log analysis	Varian's Linear accelerators' log, Elekta's linear accelerators' log	Varian's Linear accelerators' log, Elekta's linear accelerators' log	N/A
Beam type	Photon	Photon, electron	Photon
Dose calculation algorithm	Monte Carlo algorithm	CCC/S algorithm for photo, PBRA algorithm for electron	Monte Carlo algorithm
Dose comparison	Yes	Yes	Yes
Displaying of inspection results	Yes	Yes	Yes

7. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Software Verification and Validation Testing (Non-Clinical Testing)

Software verification and validation 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.

Test results demonstrate conformance to applicable requirements and specifications. No animal studies or clinical tests have been included in this premarket submission.

Secondary Dose Calculation verification test

A verification test for the the secondary dose calculation of the subject device was perform for 20 patients that have been treated with IMRT and VMAT techniques. For each tumor location, there are 10 samples for Head and Neck cancers, 5 samples for Chest cancers and 5 samples for Abdomen samples, including Brain , Lung, Head and Neck, and GI cancers. The joint testing devices include two FDA-cleared LINACs and two FDA-cleared TPS systems from different vendors. The results of all test cases passed the test criteria and the following items were checked during the test: The dose - volume histogram (DVH), dose index, 3D dose distribution, dose profile, gamma distribution, pass/fail results for the dose - volume histogram (DVH) limits, the 3D gamma passing rate, and differences in dose indices between the subject device and the FDA cleared TPS.

8. Standards Conformance

The subject device conforms in whole or in part with the following standards:

• IEC 62366-1:2015 Medical device Part 1 – Application of usability engineering to medical devices

• IEC 61217:2011 Radiotherapy Equipment – Coordinates, Movements and Scales

• IEC 62304:2006+A1:2015 Medical device software – Software life cycle processes

Further, during the development, potential hazards were controlled by a risk management plan including risk analysis, risk mitigation, verification and validation.

9. CONCLUSION

AccuCheck is believed to be substantially equivalent to the predicate device in terms of its indications for use, technical characteristics, and overall performance. The information provided in this submission indicates substantial equivalence to the predicate device.

Therefore, Manteia Technologies Co., Ltd. considers the subject device, **AccuCheck**, is substantially equivalent to the predicate device **Mobius3D v4.0 (K203669)**.