



October 24, 2025

Manteia Technologies Co., Ltd.  
Chao Fang  
Quality Manager  
Unit 3001-3005, No.5 Huizhan North Road  
Xiamen, Fujian 361008  
China

Re: K250696  
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: March 7, 2025  
Received: March 7, 2025

Dear Chao Fang:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Lora D. Weidner". The signature is written in a cursive style. A large, semi-transparent blue "FDA" watermark is visible in the background behind the signature.

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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K250696

?

Please provide the device trade name(s).

?

AccuCheck

Please provide your Indications for Use below.

?

AccuCheck is a quality assurance software to the quality assurance of general offline planning, online adaptive planning and various radiotherapy technology such as photon and proton. It is 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 Accelerator 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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

## 510(k) Summary

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

The assign 510(k) Number: K250696

### I. SUBMITTER

Manteia Technologies Co., Ltd.

Unit 3001-3005, No.5 Huizhan North Road, Xiamen City, Xiamen, Fujian, P.R. China

Establishment Registration Number: 3016686005

Contact Person: Chao Fang

Position: Quality Manager

Email: ra@manteiatech.com

Date of Prepared: 03/07/2025

### II. DEVICE

Subject Device/Trade Name: AccuCheck

Common Name: AccuCheck Radiotherapy Plan Quality Assurance System

Classification Name: accelerator, linear, medical

Classification: II

Product Code: IYE

Regulation Number: 21 CFR 892.5050

Review Panel: Radiology

### III. PREDICATE DEVICE

Predicate Device: AccuCheck 1.1 (K223834)

### IV. DEVICE DESCRIPTION

AccuCheck, defined as a radiotherapy plan quality assurance system, aims to improve the clinical efficiency of offline and online quality control. AccuCheck supports Monte Carlo dose calculation engine, and is applicable to the quality assurance of general offline planning, online adaptive planning and various radiotherapy technology such as photon and proton.

AccuCheck is to be used for the quality assurance of offline plans and online adaptive radiotherapy plans, where the TPS Check module is used to check whether the parameters related to treatment plan are within the executable range of the machine; the Dose Check module is designed to use an independent dose calculation engine to re-calculate the original plan before the treatment, and is compared with the dose of the original plan; the Transfer Check module could verify whether errors are occurred during transferring from the TPS system to the accelerator; the Log Check module is used to obtain execution log of each

execution of the accelerator, calculate dose through an independent dose calculation engine, and compare it with the dose of original plan; Treatment Summary supports physical dose accumulation of doses executed multiple times for a single plan, which reflect the stability of the accelerator operating, it could at the same time support the reconstruction of log to the fractional images so as to evaluate the daily exposure dose of the patient. AccuCheck provides abundant auxiliary analysis tools, including DVH Graph, Gamma Analysis, Target Coverage, Gamma Pass Rate of each ROI, Dose Statistics, and Clinical Goals Evaluation.

## V. INDICATIONS FOR USE

AccuCheck is a quality assurance software to the quality assurance of general offline planning, online adaptive planning and various radiotherapy technology such as photon and proton. It is 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 Accelerator 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.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The main changes in the subject device compared with the predicate device are as follow:

- Dose Check Feature
  - New-add Treatment Techniques - TomoTherapy and Pencil Beam Scanning ( PBS)
  - New-add Beam type - Proton
- Log Check Feature
  - New-add Treatment Techniques - Pencil Beam Scanning ( PBS)
  - New-add Beam type - Proton

The detailed comparison of technical parameters is shown in the table below.

ITEM	Subjective Device AccuCheck	Predicate Device AccuCheck (K223834)
Regulatory Information		
Regulation No.	21CFR 892.5050	21CFR 892.5050
Product Code	IYE	IYE
Class	II	II
Indications of Use	AccuCheck is a quality assurance software to the quality assurance of general offline planning, online adaptive planning and various radiotherapy technology such as photon and proton. It is used for data transfer integrity check, secondary dose calculation with Monte Carlo	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

## 510(k) Summary

	algorithm, and treatment plan verification in radiotherapy. AccuCheck also provides independent dose verification based on Accelerator 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.	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.
Intended User	Trained radiation oncology personnel.	Trained radiation oncology personnel.
Operating System	Windows	Windows
Independent Software	YES	YES
<b>Technological Characteristics</b>		
TPS Check	YES	YES
Dose Check	YES	YES
Transfer Check	YES	YES
Log Check	YES	YES
<b>Patient Management Feature</b>		
Auto Check	YES	YES
Manual Check	YES	YES
Patient List Display	YES	YES
Plan List Display	YES	YES
Plan Check Results Display	YES	YES
DICOM RT	YES (Supports CT, CBCT, MR, RTStruct, RTPlan, RTDose)	YES (Supports CT, CBCT, MR, RTStruct, RTPlan, RTDose)
<b>TPS Check Feature</b>		
Supported Treatment Techniques	3D-CRT, IMRT, VMAT, SRS, SBRT	3D-CRT, IMRT, VMAT, SRS, SBRT
Check Results Display	YES	YES
Check Results Export	YES	YES
<b>Dose Check Feature</b>		
Supported Treatment Techniques	3D-CRT, IMRT, VMAT, SRS, SBRT, TomoTherapy, PBS	3D-CRT, IMRT, VMAT, SRS, SBRT
Supported DICOM Data	CT, CBCT, MR, RTStruct, RTPlan, RTDose	CT, CBCT, MR, RTStruct, RTPlan, RTDose
Beam Type	Photon, Proton	Photon
Dose Calculation Algorithm	Monte Carlo algorithm	Monte Carlo algorithm

## 510(k) Summary

Dose Comparison	YES	YES
Check Results Display	YES	YES
Check Results Export	YES	YES
<b>Transfer Check Feature</b>		
Supported Treatment Techniques	3D-CRT, IMRT, VMAT, SRS, SBRT	3D-CRT, IMRT, VMAT, SRS, SBRT
Consistency Check based on transferred plan	YES	YES
Check Results Display	YES	YES
Check Results Export	YES	YES
<b>Log Check Feature</b>		
Accelerator Log Analysis	Varian accelerators' log files, Elekta accelerators' log files	Varian accelerators' log files, Elekta accelerators' log files
Supported Treatment Techniques	3D-CRT, IMRT, VMAT, SRS, SBRT, PBS	3D-CRT, IMRT, VMAT, SRS, SBRT
Beam Type	Photon, Proton	Photon
Dose Calculation Algorithm	Monte Carlo algorithm	Monte Carlo algorithm
Dose Comparison	YES	YES
Check Results Display	YES	YES
Check Results Export	YES	YES

**VII. PERFORMANCE DATA**

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

**Biocompatibility Testing**

AccuCheck is a standalone software and will not come in contact with the patient, thus biocompatibility testing is not applicable.

**Electrical Safety and Electromagnetic Compatibility (EMC)**

Not Applicable (Standalone Software).

**Software Verification and Validation Testing**

Software verification and validation testings were conducted, and documentation was provided as recommended by *FDA's Guideline for Industry and FDA Staff - Content of Premarket Submission for Device Software Functions*. Verification and validation of the software was conducted to ensure that the product meet users needs and intended use. AccuCheck passed all software verification and validation tests.

#### Compatibility Test of AccuCheck with TPS and Accelerator

The compatibility test was performed for 2 samples including treatment plans and treatment logs. The test samples used a compatible combination of Accelerator and TPS. The result of all test cases were passed and the following items were checked during the test: 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.

The test validates the compatibility of AccuCheck with TPS and Accelerator, for which are typical equipment from Varian, Elekta and Accuray.

#### Verification and Validation Test on Secondary Dose Calculation

The test was performed for 20 patients respectively with Brain, Lung, Head and Neck, and GI cancers that have been treated with IMRT, VMAT, TOMO and Proton techniques. The result of all test cases were passed 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.

#### **Mechanical and Acoustic Testing**

Not Applicable (Standalone Software).

#### **Animal Study**

Not Applicable (Standalone Software).

#### **Clinical Studies**

Clinical trials were not performed as part of the development of this product. Clinical testing on patients is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk.

#### **VIII. CONCLUSIONS**

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 subjective device, **AccuCheck**, is substantially equivalent to the predicate device **AccuCheck (K223834)**.