Wisdom Technologies., Inc.
℅ Wei Wang
Consultant
11 Longstreet
IRVINE, CA 92620

January 5, 2024

Re: K231273
Trade/Device Name: ArcherQA (V1.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: December 5, 2023
Received: December 5, 2023

Dear Wei Wang:

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.

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) 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
and Radiation Therapy Devices
OHT8: Office of 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.

Submission Number *(if known)*

K231273

Device Name

ArcherQA (V1.0)

Indications for Use *(Describe)*

ArcherQA is a software product intended to provide quality assurance of a radiation treatment plan generated by a commercial treatment planning system (TPS) by allowing a clinician to re-calculate dose parameters with dose calculation algorithms independent from the commercial TPS and compare the two set of dose information. ArcherQA is not a TPS 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.

510(k) Summary

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

I. SUBMITTER

Name: Wisdom Technologies., Inc.

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Contact Person: Wei Wang, Consultant, Regulatory Affairs
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Date Prepared: April 26, 2023

II. DEVICE

Subject Device Name: ArcherQA v1.0
Common/Trade Name: ArcherQA
Product Code and Classification: Medical charged-particle radiation therapy system
IYE | 21 CFR 892.5050 | Class II

III. PREDICATE DEVICES

Primary: K180595 SciMoCa (Radialogica LLC)
Reference: K203669 Mobius3D (Varian Medical Systems, Inc.)

IV. DEVICE DESCRIPTION

ArcherQA (v1.0) is a standalone software product used within a radiation therapy clinic for quality assurance (Q A) and treatment plan verification via recalculation of the dose with a GPU-based independent Monte Carlo dose calculation algorithm. ArcherQA is neither a radiation delivery device (e.g. a linear accelerator) nor a Treatment Planning System (TPS). ArcherQA cannot design or transmit instructions to a delivery device or control any other medical device. ArcherQA is an analysis tool meant solely for QA purposes when used by trained medical professionals. Being a software-only QA tool, ArcherQA never comes into contact with patients.

ArcherQA performs dose calculation verifications for radiation treatment plans by independently calculating radiation dose. Using both algorithm and hardware-enhanced Monte Carlo methods, ArcherQA can verify the final dose for radiotherapy plans. The calculation is based on read-in treatment plans that are initially calculated by a TPS. ArcherQA supports photon and electron dose calculation. The treatment modalities that can be evaluated by ArcherQA include: three-dimensional conformal radiotherapy (3D CRT), intensity-modulated radiotherapy (IMRT), volumetric modulated arc therapy (VMAT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT).

ArcherQA also performs dose delivery QA by using the measurement data recorded in a linear accelerator's delivery log files to compare with calculated the delivery dose. This is presented to the end user in a software component of ArcherQA called Fraction Check.

V. INDICATIONS FOR USE

ArcherQA is a software product intended to provide quality assurance of a radiation treatment plan generated by a commercial treatment planning system (TPS) by allowing a clinician to re-calculate dose parameters with dose calculation algorithms independent from the commercial TPS and compare the two set of dose information. ArcherQA is not a TPS 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 PREDICATE DEVICES

The primary technological components of ArcherQA and its predicate devices are independent dose calculation algorithms and functionalities that allow comparison between an independently-calculated dose information and those generated by a commercial TPS for the purpose of quality assurance. Both are software devices that receive inputs related to radiological images to estimate absorbed dose using the well-established algorithms; Both are software devices for prescription use in a professional environment with no patient contact.

There are no known differences in technological characteristics between the subject device and the predicate devices that raise any questions of safety or effectiveness. The technological characteristics of the subject device are believed to be substantially equivalent to the predicate devices.

Substantial Equivalence Comparison Table

Area of Comparison	Subject Device-ArcherQA	Primary-SciMoCa(K180595)	Reference-Mobius3D (K203669)
Regulation Number/code	21 CFR 892.5050|IYE	21 CFR 892.5050|IYE	21 CFR 892.5050 |IYE
Regulation Name	Medical charged-particle radiation therapy system	Medical charged-particle radiation therapy system	Medical charged-particle radiation therapy system
Indications for Use	ArcherQA is a software product intended to provide quality assurance of a radiation treatment plan generated by a commercial treatment planning system (TPS) by allowing a clinician to re-calculate dose parameters with dose calculation algorithms independent from the commercial TPS and compare the two set of dose information. ArcherQA is not a TPS or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance purposes.	SciMoCa is a software product intended to provide quality assurance of a radiotherapy dose calculated by a treatment planning system by allowing a clinician to re-calculate the dose with an independent dose calculation algorithm and compare the two doses. SciMoCa 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 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.
Algorithm	Monte Carlo	Monte Carlo	Collapsed Cone Convolution/Superposition
Input	Plan parameters	Plan parameters	Plan parameters
Output	3D dose calculation	3D dose calculation	3D dose calculation

Dose Map Format	DICOM RT3.0	DICOM RT3.0	DICOM RT3.0
types of dose calculations	photon, electron	photon, electron	photon, electron
Types of image files supported	CT images	CT images	CT images
Ttreatment types	3D, IMRT, VMAT, SBRT, SRS	3D, IMRT, VMAT, SBRT, SRS	IMRT, VMAT, dynamic / virtual wedge, SRS
Analysis modes	• DVH Graph • Target Coverage • DVH Limits • 3D Gamma • Beam Information • ROI Overview • Notes and Approvals	• DVH Graph • Target Coverage • DVH Limits • 3D Gamma • Beam Information • ROI Overview • Notes and Approvals	• DVH Graph • Target Coverage • DVH Limits • 3D Gamma • Beam Information • ROI Overview • Notes and Approvals
Usage Environment	for prescription use in a professional environment by trained radiation oncology personnel	for prescription use in a professional environment by trained radiation oncology personnel	for prescription use in a professional environment by trained radiation oncology personnel
Patient Contact	None	None	None

VII. PERFORMANCE DATA

Software verification and validation were conducted, and the process was documented per FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."*

Verification and Validation tests were executed to verify that the product performed to specifications and worked as designed. Test results demonstrate conformance to applicable requirements and specifications. Bench testing against the predicate device SciMoCa with 30 randomly selected samples from available database demonstrates good agreement, proving that both devices can be used as equivalent third-party independent software for clinical dose verification in radiotherapy. No animal studies or clinical tests were required for validation of the software.

VIII. CONCLUSION

ArcherQA is believed to be substantially equivalent to predicate devices in terms of its indications for use, technical characteristics, and overall performance. The information provided in this submission indicates the subject device is as safe, is as effective, and performs as well as predicate devices. Therefore, it is in the opinion of Wisdom Technologies, Inc. that the medical device, ArcherQA, is substantially equivalent to predicate devices.