April 10, 2026

AItewan BioMedical Technology Inc.
Ya-Xuan Yang
7F., No. 1, Yumin 6th Rd., Beitou Dist.
Taipei,
Taiwan

Re: K252190
Trade/Device Name: DeepBT Detector-Plus
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: July 14, 2025
Received: July 14, 2025

Dear Ya-Xuan Yang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) 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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252190

Device Name
DeepBT Detector-Plus

Indications for Use *(Describe)*
DeepBT Detector-Plus is a software system intended to assist trained medical professionals, during their clinical workflows of radiation therapy treatment planning, by providing initial object contours of diagnosed brain tumors (i.e., region of interest, ROI). The system can utilize both axial T1-weighted contrast-enhanced brain MRI images (T1W+C) and T2-weighted (T2W) MRI images, allowing the model to reference both imaging sequences simultaneously. The generated contours are applied on the T1W+C images, which serve as the primary imaging reference for radiation therapy treatment planning.

DeepBT Detector-Plus, which utilizes an artificial intelligence algorithm (i.e., deep learning neural networks), is intended to be used only on adult patients for generating Gross Tumor Volume (GTV) contours of brain metastases, meningiomas, and acoustic neuromas; It is not intended to be used with images of other types of brain tumors. When inputting images, DeepBT Detector-Plus can take either single-parameter images (T1W+C) or bi-parameter images (T1W+C and T2W) for interpretation.

Medical professionals must finalize (confirm or modify) the contours generated by DeepBT Detector-Plus using an external platform available at the facility that supports DICOM-compatible viewing and editing, such as a Treatment Planning System (TPS) or a DICOM-compliant workstation, before using them for treatment.

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 – K252190

1. Submitter

Submitter	AItewan BioMedical Technology Inc.
Address	7F., No. 1, Yumin 6th Rd., Beitou Dist. Taipei City 112042, Taiwan (R.O.C)
Contact Person	Wan-Yuo Guo, M.D., Ph.D. (President)
Contact Information	886-2-2826-7169 ra.dept@aitewan-bio.com
Date Prepared	April 10, 2026

2. Proposed Device

Trade Name	DeepBT Detector-Plus
Common Name	Radiological image processing software for radiation therapy
Classification Name	Medical image management and processing system
Regulatory Number	21 CFR 892.2050
Product Code	QKB
Regulatory Class	Class II

3. Predicate Device

Predicate Device: VBrain, K203235, Vysioneer Inc.

4. Device Description

DeepBT Detector-Plus is an Artificial Intelligence (AI) software system which consists of a Web User Interface (Web UI) and a Brain Tumor AI Contouring module. The Web UI allows users to select medical images and submits them to the Brain Tumor AI contouring module for processing. Based on the magnetic resonance (MR) images selected by the user, the AI contouring module performs inferences for three types of brain tumors (acoustic neuroma, meningioma, and brain

metastasis) and provides the contouring result. The result is provided in DICOM Presentation State (PR) and Radiotherapy Structure Sets (RTSS) format for DICOM-compliant systems.

DeepBT Detector-Plus accepts T1-weighted contrast-enhanced (T1W+C) MR images and T2-weighted (T2W) MR images. When inputting images, the software can handle either single parametric MR images (T1W+C) or bi-parametric images (T1W+C and T2W) without requiring manual preprocessing or labeling. It automatically analyzes the images and provides contours of brain tumors (acoustic neuroma, meningioma, and brain metastasis).

The software is configured to work on a PACS network. Upon a user's request, it retrieves patient scans and sends them to the Brain Tumor AI Contouring module. The device then utilizes deep learning neural networks to generate brain tumor contours. The results are exported as DICOM PR and DICOM RT Structure Set (RTSS) objects and sent back to the network. These objects allow medical professionals to view or edit the contours on third-party software systems that adhere to the DICOM standard, such as treatment planning systems (TPS) or picture archiving and communication systems (PACS). Medical professionals must finalize (confirm or modify) the contours generated by DeepBT Detector-Plus before using them for treatment.

5. Indication for Use

DeepBT Detector-Plus is a software system intended to assist trained medical professionals, during their clinical workflows of radiation therapy treatment planning, by providing initial object contours of diagnosed brain tumors (i.e., region of interest, ROI). The system can utilize both axial T1-weighted contrast-enhanced brain MRI images (T1W+C) and T2-weighted (T2W) MRI images, allowing the model to reference both imaging sequences simultaneously. The generated contours are applied on the T1W+C images, which serve as the primary imaging reference for radiation therapy treatment planning.

DeepBT Detector-Plus, which utilizes an artificial intelligence algorithm (i.e., deep learning neural networks), is intended to be used only on adult patients for generating Gross Tumor Volume (GTV) contours of brain metastases, meningiomas, and acoustic neuromas; It is not intended to be used with images of other types of brain tumors. When inputting images, DeepBT Detector-Plus can take either single-parameter images (T1W+C) or bi-parameter images (T1W+C and T2W) for interpretation.

Medical professionals must finalize (confirm or modify) the contours generated by DeepBT Detector-Plus using an external platform available at the facility that supports DICOM-compatible viewing and editing, such as a Treatment Planning System (TPS) or a DICOM-compliant workstation, before using them for treatment.

6. Comparison of Technological Characteristics with Predicate Device

DeepBT Detector-Plus is substantially equivalent to the predicate device VBrain (K203235).

The proposed device, DeepBT Detector-Plus, and the predicate, VBrain, are both software devices that utilize deep learning algorithms for brain tumor detection and contouring, focusing on the same three types of brain tumors: brain metastases, meningiomas, and acoustic neuromas. Both systems are designed to assist in radiation therapy treatment planning. They integrate with PACS networks, enabling automated tumor contouring, and output results in DICOM standard formats, allowing medical professionals to view or edit the contours using DICOM-compatible third-party systems.

The only difference between the two products is that DeepBT Detector-Plus can perform AI model inference based on single-parametric MR images (T1W+C) as well as bi-parametric MR images (T1W+C and T2W). Since T2W images can provide higher signal intensity in certain cases, such as cystic tumors, they offer improved tumor boundary identification, allowing DeepBT Detector-Plus to deliver more accurate tumor contours. In contrast, VBrain supports only single-parametric images (T1W+C). However, both products focus on the same tumor types and intended clinical use, and there is no fundamental difference in their clinical applications.

Although there are differences in technical characteristics, the performance of DeepBT Detector-Plus on both single-parametric and bi-parametric images has been validated, and the results are comparable to those of the predicate device. Furthermore, the contours predicted by both products require confirmation or modification by medical professionals before they can be used for treatment planning. The information provided by both products is intended as support and does not aim to alter the clinical workflow of medical professionals. Therefore, the new product does not raise any new concerns regarding substantial equivalence.

Please refer to **Table 1** for a comparison of the intended use and key technical characteristics of the proposed device and the predicate device.

Table 1. Comparison with Predicate Device

Item	**Proposed Device**	**Predicate Device**
Company	**AItewan BioMedical Technology Inc.**	**Vysioneer Inc.**
Device Name	DeepBT Detector-Plus	VBrain
510(k) Number	Pending	K203235

Regulation No.	21 CFR 892.2050	21 CFR 892.2050
Classification	II	II
Product Code	QKB	QKB
Intended Use/Indication of Use	DeepBT Detector-Plus is a software system intended to assist trained medical professionals, during their clinical workflows of radiation therapy treatment planning, by providing initial object contours of diagnosed brain tumors (i.e., region of interest, ROI). The system can utilize both axial T1-weighted contrast-enhanced brain MRI images (T1W+C) and T2-weighted (T2W) MRI images, allowing the model to reference both imaging sequences simultaneously for improved accuracy. The generated contours are applied on the T1W+C images, which serve as the primary imaging reference for radiation therapy treatment planning. DeepBT Detector-Plus, which utilizes an artificial intelligence algorithm (i.e., deep learning neural networks), is intended to be used only on adult patients for generating Gross Tumor Volume (GTV) contours of brain metastases, meningiomas, and acoustic neuromas; It is not intended to be used with images of other types of brain tumors. When inputting images, DeepBT Detector-Plus can take either single-parameter images (T1W+C) or bi-parameter images (T1W+C and T2W) for interpretation.	VBrain is a software device intended to assist trained medical professionals, during their clinical workflows of radiation therapy treatment planning, by providing initial object contours of known (diagnosed) brain tumors (i.e., region of interest, ROI) on axial T1 contrast-enhanced brain MRI images. VBrain uses an artificial intelligence algorithm (i.e., deep learning neural networks) to contour (segment) brain tumor on MRI images for trained medical professionals' attention, which is meant for informational purposes only and not intended for replacing their current standard practice of manual contouring process. VBrain does not alter the original MRI image, nor does it intend to be used to detect tumors for diagnosis. VBrain is intended only for generating Gross Tumor Volume (GTV) contours of brain metastases, meningiomas, and acoustic neuromas on axial T1 contrast-enhanced MRI images; It is not intended to be used with images of other brain tumors. The user must know the tumor

	Medical professionals must finalize (confirm or modify) the contours generated by DeepBT Detector-Plus using an external platform available at the facility that supports DICOM-compatible viewing and editing, such as a Treatment Planning System (TPS) or a DICOM-compliant workstation, before using them for treatment.	type when they use VBrain. VBrain is intended to be used on adult patients only. Medical professionals must finalize (confirm or modify) the contours generated by VBrain, as necessary, using an external platform available at the facility that supports DICOM-RT viewing/editing functions, such as image visualization software and treatment planning system.
Segmentation (Contouring) Technology	Deep learning	Deep learning
Operating System	Linux operating system	Linux operating system
User Population	Trained medical professionals include, but are not limited to, radiation oncologists, neurosurgeons, and radiologists.	Trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists, and physicists.
Supported Modalities	Axial T1-weighted contrast-enhanced brain MRI images (T1W+C) and T2-weighted (T2W) MRI images can be used. The system can accept either T1W+C images alone or both T1W+C and T2W images simultaneously.	Axial T1 contrast-enhanced MRI images
Localization and Definition of Objects (ROI)	Qualified brain tumors - brain metastases, meningiomas, and acoustic neuromas.	Qualified brain tumors - brain metastases, meningiomas, and acoustic neuromas.

Performance Testing	To evaluate the standalone analytical performance of DeepBT Detector-Plus in detecting and contouring brain tumors on T1-weighted contrast-enhanced (T1W+C) and T2-weighted (T2W) magnetic resonance (MR) images, and to demonstrate Substantial Equivalence (SE) to the predicate, AItewan conducted a multicenter, multinational, retrospective standalone performance study. The test dataset consisted of 136 cases with 360 tumors, acquired from 16 different institutions (15 in the US and 1 non-US). The performance of DeepBT Detector-Plus was assessed based on single-parameter MR images (T1W+C) and bi-parametric MR images (T1W+C and T2W). The evaluation involved comparing tumor contouring results from DeepBT Detector-Plus with ground truth using five metrics: (1) lesion-wise sensitivity, (2) false positive rate, (3) lesion-wise Dice coefficient, (4) balanced average Hausdorff distance, and (5) centroid distance. The results demonstrate that the performance of the proposed device is comparable with that of the predicate device. Software verification and validation testing were conducted, and documentation was provided following the FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" for software devices identified as "Enhanced Documentation	To support the intended use of the VBrain AI software for brain tumor contouring (segmentation) performance, Vysioneer conducted a retrospective, blinded, multicenter, multinational study with VBrain. The test dataset comprised 116 cases with 238 tumors acquired from 4 institutions (3 in the US and 1 non-US). The evaluation involved five metrics: (1) lesion-wise sensitivity, (2) false-positive rate, (3) lesion-wise Dice coefficient, (4) average Hausdorff distance, and (5) average centroid distance between VBrain's segmentation and clinicians' segmentation. All the metrics were demonstrated to pass the performance goals. Software verification and validation testing were conducted, and documentation was provided following the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for software devices identified as Major Level of Concern related to radiation therapy treatment planning.

	Level".	

7. Performance Data

7.1 Software Verification and Validation

Software verification and validation (V&V) testing were performed, and the corresponding documentation was provided in accordance with the FDA guidance, "*Content of Premarket Submissions for Device Software Functions*," issued on June 14, 2023, adhering to the **Enhanced Documentation Level** for software functions related to radiation therapy treatment planning.

In addition, the following standards have also been consulted during the software V&V activities:

- IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes
- ISO 14971:2019 Medical devices - Applications of risk management to medical device

The Software V&V activities and documentation are based on the Enhanced Documentation Level.

7.2 Training Dataset

The DeepBT Detector-Plus model was trained on a retrospective dataset comprising 2,867 patients, including 510 cases of acoustic neuroma, 1,180 cases of meningioma, and 1,177 cases of brain metastasis. All patients underwent Gamma Knife radiosurgery. The training dataset included imaging acquired at the time of treatment for all patients, and follow-up imaging when available. The dataset was collected from two major medical centers in Taiwan between 1999 and 2022.

7.3 Standalone Performance Testing

AItewan conducted a multicenter, multinational, retrospective study to evaluate the standalone analytical performance of the artificial intelligence software for assisting in brain tumor contouring on T1W+C and T2W MR imaging. The test dataset consisted of 136 cases with 360 lesions, retrospectively collected from 16 different institutions (15 in the US and 1 non-US). The ground truth was established by the consensus of three US board-certified radiologists with fellowship training in neuroradiology or MRI with at least five years of post-fellowship experience.

By comparing tumor contouring between DeepBT Detector-Plus and the ground truth, five metrics were evaluated: (1) lesion-wise sensitivity, (2) false positive rate, (3) lesion-wise Dice coefficient, (4) balanced average Hausdorff distance (bAHD), and (5) centroid distance of DeepBT Detector-Plus's inference results for the brain tumors.

The standalone performance evaluation was conducted using a pre-specified statistical analysis plan. Lesion-wise sensitivity was used for sample size determination based on a statistical hypothesis testing approach. Performance of DeepBT Detector-Plus was evaluated by comparison to the predicate device across multiple metrics, including lesion-wise sensitivity, false positive rate, lesion-wise Dice coefficient, and centroid distance. A predefined success threshold for bAHD was established as ≤ 5.6%, based on the upper bound of the 95% confidence interval of the predicate device's average Hausdorff distance.

The tables below present the performance of DeepBT Detector-Plus in tumor detection and contouring across five metrics, evaluated using bi-parametric MR images (**Table 2**) and single-parametric MR images (**Table 3**).

Additional subgroup analyses were performed by MRI manufacturer, tumor type, lesion size, and MRI image voxel size. MRI manufacturers included major vendors such as GE, Philips, Siemens, Hitachi, and other manufacturers. Tumor types included acoustic neuroma, meningioma, and brain metastasis. Lesion size was categorized into three groups: ≤10 mm, >10 to ≤20 mm, and >20 mm. MRI image voxel size was categorized into ≤1 mm^3 and >1 mm^3.

Performance was generally consistent across the evaluated tumor types, major MRI manufacturers, and MRI image voxel size subgroups within the validated ranges. Greater performance variability was observed for small lesions (≤10 mm), which may be related to technical challenges such as limited spatial resolution and partial-volume effects in clinical MRI.

The demographic distribution of the dataset:

- Sex: 92 Female, 44 Male
- Age: Adult, range from 27 to 99 years old; the average age is 66.8 years old with a standard deviation of 13.4
- Race: 65 White, 38 Asian, 1 Black, and 32 Unknown
  Note: Race data were not available for all cases due to anonymization.

Table 2. Performance data of bi-parametric MR images (T1W+C and T2W)

Performance Metrics	**Overall Value**	**95% Confidence Interval**
Lesion-wise Sensitivity	88.6%	85.3% to 91.9%
False Positive Rate	0.537 tumors/case	0.453 to 0.621
Lesion-wise Dice Coefficient	0.809	0.793 to 0.824
Balanced Average Hausdorff Distance	3.2%	2.3% to 4.0%
Centroid Distance	5.8%	4.9% to 6.7%

Table 3. Performance data of single-parametric MR images (T1W+C)

Performance Metrics	Overall Value	95% Confidence Interval
Lesion-wise Sensitivity	88.3%	85.0% to 91.6%
False Positive Rate	0.787 tumors/case	0.718 to 0.856
Lesion-wise Dice Coefficient	0.804	0.788 to 0.820
Balanced Average Hausdorff Distance	5.2%	2.8% to 7.6%
Centroid Distance	7.2%	5.6% to 8.8%

8. Conclusions

Based on the information provided in this premarket notification, including the intended use, technological characteristics, and performance testing results, the data demonstrate that DeepBT Detector-Plus is substantially equivalent to the predicate device.