May 28, 2025

Taiwan Medical Imaging Co., Ltd.
Paul Chang
Regulatory Affairs Staff
3F., No. 1, Fuxing 4th Rd., Qianzhen Dist.,
Kaohsiung City, 806611
Taiwan

Re: K250427
Trade/Device Name: TAIMedImg DeepMets
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB, QIH
Dated: May 15, 2025
Received: May 15, 2025

Dear Paul Chang:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8B: Division of Radiologic 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.	K250427

Please provide the device trade name(s).

TAIMedImg DeepMets

Please provide your Indications for Use below.

TAIMedImg DeepMets is a software device intended to assist trained medical professionals by providing initial object contours on axial T1-weighted contrast-enhanced (T1WI+C) brain magnetic resonance (MR) images to accelerate workflow for radiation therapy treatment planning.

TAIMedImg DeepMets is intended only for patients with known (imaging diagnosed) brain metastases (BM) when cancer cells spread from primary site to the brain. It is not intended to be used with images of other brain tumors or other body parts. The software is intended for use with BM lesions with a diameter of ≥ 10 mm.

TAIMedImg DeepMets uses an artificial intelligence algorithm to contour images and offers automated segmentation for Gross Tumor Volume (GTV) contours of brain metastases. The software is an adjunctive tool and not intended for replacing the users' current standard practice of manual contouring process. All automatic output generated by the software shall be thoroughly reviewed by a trained medical professional prior to delivering any therapy or treatment. The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.

TAIMedImg DeepMets is intended to be used by medical professionals trained in the use of the device. Only DICOM images of adult patients are considered valid input. DeepMets does not support DICOM images of patients that have one of the following exclusions:

(i) presence of prior craniotomy, (ii) patients with clinical imaging diagnosis of brain tumors other than BM, (iii) Images with patient motion: excessive motion leading to artifacts that make the scan technically inadequate.

Medical professionals must finalize (confirm or modify) the contours generated by TAIMedImg DeepMets, 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.

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.

1 Submitter Information

Company Name:	**Taiwan Medical Imaging Co., Ltd.**
Address:	**3F., No. 1, Fuxing 4th Rd., Qianzhen Dist., Kaohsiung City 806611 Taiwan**
Contact Person:	**Bo-Ru Lin**
Phone:	**+886-2-25555835**
Email:	**boru.lin@ailabs.tw**
Date Prepared	**February 14, 2025**

2 Proposed Device

Trade Name:	**TAIMedImg DeepMets**
Common Name:	**DeepMets**
Classification Name	**Radiological Image Processing Software for Radiation Therapy**
Regulation Description	**Medical Image Management and Processing System**
Product Code	**QKB, QIH**
Regulation Number	**21 CFR 892.2050**
Device Class	**Class II**

3 Predicate Device

Device Name:	**VBrain**
510(k) Number:	**K203235**
Manufacturer:	**Vysioneer Inc.**
Product Code:	**QKB**

4 Device Description

TAIMedImg DeepMets is a software application system intended for use in the contouring (segmentation) of brain magnetic resonance (MR) images. The device comprises an AI inference module and a DICOM Radiotherapy Structure Sets (RTSS, or RTSTRUCT) converter module.

The AI inference module consists of image preprocessing, deep learning neural networks, and postprocessing components, and is intended to contour brain metastasis on the axial T1-weighted contrast-enhanced (T1WI+C) MR images. It utilizes deep learning neural networks to generate contours and annotations for the diagnosed brain metastases.

The DICOM RTSS converter module converts the contours, annotations, along with metadata, into a standard DICOM-RTSTRUCT file, making it compatible with radiotherapy treatment planning systems.

5 Intended Use/ Indication for Use

TAIMedImg DeepMets is a software device intended to assist trained medical professionals by providing initial object contours on axial T1-weighted contrast-enhanced (T1WI+C) brain magnetic resonance (MR) images to accelerate workflow for radiation therapy treatment planning.

TAIMedImg DeepMets is intended only for patients with known (imaging diagnosed) brain metastases (BM) when cancer cells spread from primary site to the brain. It is not intended to be used with images of other brain tumors or other body parts. The software is intended for use with BM lesions with a diameter of ≥10 mm.

TAIMedImg DeepMets uses an artificial intelligence algorithm to contour images and offers automated segmentation for Gross Tumor Volume (GTV) contours of brain metastases. The software is an adjunctive tool and not intended for replacing the users' current standard practice of manual contouring process. All automatic output generated by the software shall be thoroughly reviewed by a trained medical professional prior to delivering any therapy or treatment. The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.

TAIMedImg DeepMets is intended to be used by medical professionals trained in the use of the device.

Only DICOM images of adult patients are considered valid input. DeepMets does not support DICOM images of patients that have one of the following exclusions:

(i) presence of prior craniotomy, (ii) patients with clinical imaging diagnosis of brain tumors other than BM, (iii) Images with patient motion: excessive motion leading to artifacts that make the scan technically inadequate.

Medical professionals must finalize (confirm or modify) the contours generated by TAIMedImg DeepMets, 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.

6 Comparison with Predicate Device

The proposed device, TAIMedImg DeepMets, is substantially equivalent to the claimed predicate, VBrain (K203235). Both are AI (deep learning)-based software used in the workflow of radiation therapy for tumor contouring on MRI images and are regulated under the Product Code QKB. The primary difference is that DeepMets focused solely on Gross Tumor Volume (GTV) contours of brain metastases, while VBrain also includes meningiomas and acoustic neuromas. DeepMets is intended for use with BM lesions with a diameter of ≥ 10 mm.

Please see **Table A** below for a comparison of the intended use and key technological characteristics of the proposed device and the predicate device.

Table A. Comparison with the predicate device.

Item	Proposed Device	Predicate Device
Company	Taiwan Medical Imaging Co., Ltd.	Vysioneer Inc.
Device Name	TAIMedImg DeepMets	VBrain
510k Number	Pending	K203235
Regulation No.	21CFR 892.2050	21CFR 892.2050
Classification	II	II
Product Code	QKB, QIH	QKB
Intended Use/Indication for Use	TAIMedImg DeepMets is a software device intended to assist trained medical professionals by providing initial object contours on axial T1-weighted contrast-enhanced (T1WI+C) brain magnetic resonance (MR) images to accelerate workflow for radiation therapy treatment planning. TAIMedImg DeepMets is intended only for patients with known (imaging diagnosed) brain metastases (BM) when cancer cells spread from primary site to the brain. It is not intended to be used with images of other brain tumors or other body parts. The software is intended for use with BM lesions with a diameter of ≥ 10 mm. TAIMedImg DeepMets uses an artificial intelligence algorithm to	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., the 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

	contour images and offers automated segmentation for Gross Tumor Volume (GTV) contours of brain metastases. The software is an adjunctive tool and not intended for replacing the users' current standard practice of manual contouring process. All automatic output generated by the software shall be thoroughly reviewed by a trained medical professional prior to delivering any therapy or treatment. The physician retains the ultimate responsibility for making the final diagnosis and treatment decision. TAIMedImg DeepMets is intended to be used by medical professionals trained in the use of the device. Only DICOM images of adult patients are considered valid input. DeepMets does not support DICOM images of patients that have one of the following exclusions: (i) presence of prior craniotomy, (ii) patients with clinical imaging diagnosis of brain tumors other than BM, (iii) Images with patient motion: excessive motion leading to artifacts that make the scan technically inadequate. Medical professionals must finalize (confirm or modify) the contours generated by TAIMedImg DeepMets, 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.	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 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.
Operating System	Linux	Linux
User Population	The software is only used by trained medical professionals.	Trained medical professionals including, but not limited to, radiologists, oncologists, physicians,

		medical technologists, dosimetrists, and physicists.
Patient Population	Adult patients with known primary cancer (outside brain) and brain metastasis scheduled for radiation therapy.	Adult patients with known (diagnosed) brain metastases, meningiomas, or acoustic neuromas scheduled for radiation therapy.
Anatomical Site	Brain	Brain
Supported Modalities	Axial T1-weighted contrast-enhanced (T1WI+C) brain magnetic resonance (MR) images	Axial T1 contrast-enhanced MRI images
Localization and Definition of Objects	Known (imaging diagnosed) brain metastases with a diameter of ≥ 10 mm	Qualified brain tumors - brain metastases, meningiomas, and acoustic neuromas
Performance Testing	A performance evaluation of TAIMedImg DeepMets for brain metastasis segmentation is proceeded, the clinical testing dataset comprised 158 cases from 16 MRI scan sources in US. Five metrics are calculated and evaluated: (1) lesion-wise sensitivity, (2) false positive rate, (3) Dice Similarity Coefficient, (4) Hausdorff distance and (5) centroid distance between DeepMets' segmentation and clinicians' segmentation.	VBrain AI software for brain tumor contouring (segmentation) performance test data sets consisted of 116 cases acquired from 4 different institutions (3 US and 1 non-US). Five metrics are evaluated: (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.
Segmentation (Contouring) Technology	Deep learning	Deep learning
Design: Data Visualization/ Graphical User Interface	No	No
Design: Manual editing feature	No	No

Alteration of Original Images	No	No
Data Export	DICOM-RT	DICOM-RT

7 Performance Data

7.1 Software Verification and Validation Testing

For software design, Taiwan Medical Imaging Co., Ltd. conducted and documented the software verification and validation testing activities, in accordance with FDA's Guidance for Industry and FDA Staff, "***Content of Premarket Submissions for Device Software Functions***" dated June 14, 2023, for software devices identified as Enhanced Documentation Level.

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 DeepMets model was initially trained on a retrospective dataset of 1,029 patients with brain metastases who underwent Gamma Knife radiosurgery, collected from a major medical center in Taiwan between 1993 and 2017. Further tuning was conducted using an additional dataset from 559 patients included in a nationwide healthcare database covering the years 2018 to 2019.

7.3 Standalone Performance Testing

Standalone performance testing was conducted using an independent U.S. dataset consisting of 158 MRI scans from 158 patients with 289 measurable lesions (≥10 mm in diameter, as defined by RANO-BM criteria). The dataset included MRI scans from 16 imaging facilities, acquired using scanners from GE, Philips, Siemens, and Toshiba, with standardized parameters (axial T1WI+C with gadolinium-based contrast, slice thickness ≤ 5 mm, pixel size 0.3-1 mm, and 0-1 mm slice gap). The validation dataset was from the U.S., completely independent and not used in any stage of algorithm development.

The demographic distribution of the dataset:

Gender: 75 Female, 83 Male

Age: Adult, range from 41 to 92 years old; the average age is 66.65 years with a standard deviation of 9.72.

Ethnicity: 4 Not Hispanic or Latin, 154 Unknown

Race: 1 African American, 104 White, 53 Unknown

Note: due to anonymization, ethnicity and race information were not available for all cases.

Ground truth annotations were manually established based on consensus NRG/RTOG clinical guidelines by three clinically experienced radiologists/neuroradiologists. These annotations reflected established clinical segmentation standards for brain metastases and served as the reference standard for all performance evaluations

Primary performance endpoints of performance testing included Lesion-Wise Sensitivity (Se) and False Positive Rate (FPR), while secondary endpoints included Dice Similarity Coefficient (DSC), Hausdorff Distance (HD), and Centroid Distance (CD).

Acceptance criteria for model performance were established by referencing published benchmarks from FDA-cleared deep learning devices using deep learning for lesion detection and segmentation, along with clinical standards relevant to brain metastasis management. A summary of performance results along with the acceptance criteria is presented below:

Table B: Summary of DeepMets performance

Metric	Mean	95%CI	Acceptance Criteria	Source
Lesion-Wise Sensitivity (Se) (%)	89.97	(86.51, 93.43)	> 80	Deep learning
False-Positive Rate (FPR) (FPs/case)	0.354	(0.215, 0.481)	< 0.5	Deep learning
Dice Similarity Coefficient (DSC)	0.70	(0.67, 0.72)	≥ 0.65	Estimated
Hausdorff Distance (HD) (mm)	6.66	(5.86, 7.41)	≤ 8.0	Estimated
Centroid Distance (CD) (mm)	1.75	(1.33, 2.11)	≤ 2.0	Estimated

Note: in "Source" column above, Deep learning means similar device using deep learning technology, while Estimated indicates acceptance criteria were estimated based on the literature and clinical justification.

Subgroup analysis demonstrated consistent Se and FPR across categories including sex, age, number of metastases, lesion size, MRI magnetic field strength, slice thickness, manufacturer, and imaging source. However, slightly higher FPRs were also noted in the following groups:

- Subjects older than 71 years (FPR: 0.568 FPs/case, Se: 92.19%)

- Subjects imaged with 3T field strength (FPR: 0.509 FPs/case, Se:93.88%)
- Subjects scanned using Philips MRI devices (FPR: 0.537 FPs/case, Se: 94.90%)
- Subjects with more than 15 lesions (FPR: 0.750 FPs/case, Se: 80.0%)

These findings are included in the user documentation to guide clinical use.

The results of performance testing demonstrate that DeepMets performs as expected.

8 Conclusion

In conclusion, Taiwan Medical Imaging Co., Ltd. has conducted performance testing on TAIMedImg DeepMets. The software passed its requirements for safety and effectiveness and does not introduce any new potential safety risks. It demonstrates that TAIMedImg DeepMets is substantially equivalent to and performs at least as safely and effectively as the listed predicate devices.