Vysioneer Inc.
℅ Vicki Lin
Regulatory Specialist
33 Rogers. St., # 308
Cambridge, MA 02142

December 16, 2021

Re: K213628
Trade/Device Name: VBrain
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Dated: November 12, 2021
Received: November 17, 2021

Dear Vicki 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 and Part 809); 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,

for
Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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.

510(k) Number *(if known)*
k213628

Device Name
VBrain

Indications for Use *(Describe)*
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 and organs at risk in the brain (i.e., the region of interest, ROI) on axial T1 contrast-enhanced brain MRI images. VBrain is intended to be used on adult patients only.
VBrain uses an artificial intelligence algorithm (i.e., deep learning neural networks) to contour (segment) brain tumor and organs at risk (brain stem, eyes, optic nerves, optic chiasm) in the brain 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, and contours of organs at risk in the brain; it is not intended to be used with images of other brain tumors or other body parts. The user must know the tumor type when they use VBrain.
VBrain also contains the automatic image registration feature to register volumetric medical image data. (e.g., MR, CT). It allows rigid image registration to adjust the spatial position and orientation of two images.
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.

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.

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Vysioneer Inc.
33 Rogers St. #308, Cambridge, MA 02142
www.vysioneer.com/

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR 807.92

Submitter

Vysioneer Inc.

33 Rogers St. #308, Cambridge, MA 02142

Contact Person:	Vicki Lin
Phone:	609-865-8659
Email:	vicki.lin@vysioneer.com
Date Summary Prepared:	November 12, 2021

Device Name

Trade Name:	VBrain
Common Name:	Radiological Image Processing Software for Radiation Therapy
Classification Name:	Medical image management and processing system (21 CFR 892.2050)
Regulatory Class:	II
Product Code:	QKB

Predicate Devices

Predicate Device: VBrain

510(k) Holder/Submitter: Vysioneer Inc.

510(k) Number: K203235 (Cleared on 03/19/2021)

Predicate Device: VBrain-OAR

510(k) Holder/Submitter: Vysioneer Inc.

510(k) Number: K212116 (Cleared on 10/12/2021)

Intended Use / Indications for Use

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 and organs at risk in the brain (i.e., the region of interest, ROI) on axial T1 contrast-enhanced brain MRI images. VBrain is intended to be used on adult patients only.

VBrain uses an artificial intelligence algorithm (i.e., deep learning neural networks) to contour (segment) brain tumor and organs at risk (brain stem, eyes, optic nerves, optic chiasm) in the brain 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, and contours of organs at risk in the brain; it is not intended to be used with images of other brain tumors or other body parts. The user must know the tumor type when they use VBrain.

VBrain also contains the automatic image registration feature to register volumetric medical image data. (e.g., MR, CT). It allows rigid image registration to adjust the spatial position and orientation of two images.

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.

Device Description

VBrain is a software application system intended for use in the contouring (segmentation) of brain MRI images and in the registration of multi-modality images. The device consists of a workflow management module and 3 algorithm modules, which are the tumor contouring algorithm module, OAR contouring algorithm module, and registration algorithm module. The modules can work independently, and yet can be integrated with each other.

The tumor contouring (segmentation) algorithm module consists of image preprocessing, deep learning neural networks, and postprocessing components, and is intended to contour brain tumor on the axial T1 contrast-enhanced MR images. It utilizes deep learning neural networks to generate contours for the detected/diagnosed brain tumors and export the results as DICOM-RT objects (using the RT Structure Set ROI Contour attribute, RTSTRUCT).

The OAR contouring (segmentation) algorithm module consists of image preprocessing, deep learning neural networks, and postprocessing components, and is intended to contour organs at risk in the brain on the axial T1 contrast-enhanced MR images. It utilizes deep learning neural networks to generate contours for the organs at risk in the brain and export the results as DICOM-RT objects (using the RT Structure Set ROI Contour attribute, RTSTRUCT).

The registration algorithm module registers volumetric medical image data (e.g., MR, CT). It allows rigid image registration to adjust the spatial position and orientation of two images.

The workflow management module is configured to work on a PACS network. Upon user's request, it will pull patient scans from a PACS, and it will trigger a predefined workflow, in which different algorithm modules are executed to generate the DICOM output. The DICOM output of a workflow can be sent back to the PACS.

Comparison of Technological Characteristics with the Predicate Devices

The intended use and features of the modified device VBrain are a combination of those of the two predicate devices. The modified device uses VBrain's (K203235) tumor contouring algorithm, VBrain-OAR's (K212116) organs at risk contouring algorithm, registration algorithm and application. Each algorithm works independently and does not interfere with the others, yet they could be integrated in a predefined pipeline to work consecutively.

Same as the predicate devices, the modified device, VBrain is an AI-based (deep learning) software devices intended to be used in the workflow of radiation therapy treatment planning by providing tools to automatically segment/contour tumors and organs at risk on images as well as perform image registration (image fusion). VBrain uses the identical Deep Neural Networks and registration method as the predicates.

Minor modifications are made to increase convenience of use and improve functionality. Risk analysis and V&V testing were performed, and the results confirm that the modifications do not change the device's safety and effectiveness.

The modified device is substantially equivalent to the predicate devices because it has identical intended use, technological characteristics, and principles of operation as the predicates.

Performance Data

Regression testing was performed to verify and validate the changes of VBrain in accordance with 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.

The protocol, methods and acceptance criteria of software verification and validation testing used to evaluate the changes were not modified from those used in the predicate submission. The acceptance criteria and a summary of the results were provided for each test. VBrain passed all V&V testing, performance requirements and specifications are met.

Substantially Equivalent (SE) Conclusion

VBrain is considered substantially equivalent to the predicate devices.

Verification and validation testing and hazard analysis demonstrate that VBrain performs within its design specifications and is as safe and effective as the predicate. The minor modifications of the device do not introduce any new potential risks. Based on the information presented in these 510(k) premarket notifications, it could be concluded that the subject device VBrain is as safe and effective as the predicate devices, with the same intended use, technological characteristics, and principles of operation.