August 12, 2024

Rebrain, SAS
Thomas Queuche
Quality and Regulatory Affairs Manager
Plateforme Technologique d'Innovation Biomédicale (PTIB)
Hôpital Xavier Arnozan Avenue du Haut Lévêque
Pessac, 33600
France

Re: K242054
Trade/Device Name: OptimMRI (v2)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: July 12, 2024
Received: July 15, 2024

Dear Thomas Queuche:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242054

Device Name

OptimMRI (v2)

Indications for Use *(Describe)*

OptimMRI is a software application intended to aid qualified medical professionals in processing, visualizing, and interpreting anatomical structures from medical images. The software can be used to process pre-operative DICOM compatible MR images to generate 3D annotated models of the brain that aid the user in neurosurgical functional planning. The annotated MR images can further be used in conjunction with other clinical methods as an aid in localization of the Subthalamic Nuclei (STN) and Ventral Intermediate Nucleus (VIM) regions of interest.

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.

Submitter's Name:	RebrAIn, SAS
Address:	Plateforme Technologique d'Innovation Biomédicale (PTIB) Hôpital Xavier Arnozan Avenue du Haut Lévêque 33600 Pessac, France
Contact:	Thomas QUEUCHE, Quality and Regulatory Affairs Manager
Telephone:	+33 5 57 10 28 58
Date:	July 12, 2024
Trade Name:	OptimMRI (v2)
Model No:	N/A
Regulation description:	Medical Image Management and Processing System
Regulation number:	21 CFR 892.2050
Classification Number(s):	Primary product code : QIH Secondary product code : LLZ
Regulatory Class:	Class II
Predicate Device:	K230150 – OptimMRI, REBRAIN SAS
Reference Devices:	K213930 - Brainlab Elements Guide XT, Guide 3.0, Brainlab AG DEN210003 - SureTune4 Software, Medtronic

Device Description:

OptimMRI (v2) is a software application for processing medical images of the brain that enables 3D visualization and analysis of anatomical structures. Specifically, the software can be used to read DICOM compatible pre-operative MR images acquired by commercially available imaging devices. These images can be processed to generate 3D markers in specific regions of the brain to allow qualified medical professionals to display, review, analyze, annotate, interpret, export, and plan neurosurgical functional procedures. OptimMRI (v2) is used as an aid to localize regions of the brain such as Subthalamic Nuclei (STN) and Ventral Intermediate Nucleus (VIM) using advanced image processing techniques and machine learning models trained on a proprietary clinical database. The software supports workflow for creating pre-operative plans prior to carrying out the intraoperative procedure.

OptimMRI (v2) is configured as web-based software and its output is compatible with neurosurgical planning software supporting 3D DICOM format. Three models have been implemented within OptimMRI (v2) to segment the following regions of interest of the brain:

- STN region of interest (STN itself)
- Inferior part of the Ventral Intermediate Nucleus (VIM) and Zona Incerta
- Inferior-lateral part of the Ventral Intermediate Nucleus (VIM)

OptimMRI (v2) complies with the following standards:

- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes

- IEC 82304-1 Edition 1.0 2016-10, Health software - Part 1 : General requirements for product safety
- ISO 14971 Third Edition 2019-12, Medical devices - Application of Risk Management to medical devices
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices
- AAMI CR34971:2022, Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning
- IEC/TR 80002-1 Edition 1.0 2009-09, Medical device software - Part 1 : Guidance of the application of ISO 14971 to medical device
- ISO 20417 First edition 2021-04 Corrected version 2021-12, Medical devices - Information to be supplied by the manufacturer
- ISO 15223-1 Fourth edition 2021-07, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- ANSI UL 2900-1 First Edition 2017, Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements.
- IEC 80001-1 Edition 1.0 2010-10 Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities.
- AAMI TIR57:2016, Principles for medical device security - Risk management
- ANSI AAMI SW96:2023, Standard for medical device security - Security risk management for device manufacturers

Indications for Use:

OptimMRI (v2) is a software application intended to aid qualified medical professionals in processing, visualizing, and interpreting anatomical structures from medical images. The software can be used to process pre-operative DICOM compatible MR images to generate 3D annotated models of the brain that aid the user in neurosurgical functional planning. The annotated MR images can further be used in conjunction with other clinical methods as an aid in localization of the Subthalamic Nuclei (STN) and Ventral Intermediate Nucleus (VIM) regions of interest.

Comparison to Predicate Device

The OptimMRI (v2) software is substantially equivalent to the previously cleared predicate OptimMRI (K230150). Briefly, the subject and predicate devices are based on the following same technological elements:

- Import, reading and storage of MR images in 3D DICOM format;
- Rotation, scaling, magnification (zoom) of the image
- Navigation through MRI slices;
- Selecting AC, PC and MP landmarks
- Semi-automatic segmentation process
- Implementation of models to generate STN or VIM regions of interest and convert them into 3D crosses where the center of the cross is the position calculated by the model;
- Output annotated MR images with 3D crosses in DICOM format

The only technical difference consists of the addition of a new model in the subject device to help localize the inferior-lateral-region of the VIM. Verification and validation testing for OptimMRI (v2) software demonstrates that the identified minor technical differences do not raise any new safety or efficacy concerns during the controlled software development process.

Testing to Support the Software Modifications (Non-Clinical Testing) :

Following the modifications, extensive verification and validation testing was conducted to validate that the software functions as specified and performs similarly to the predicate device using the same acceptance criteria and the same test methods as used for the previously cleared predicate device.

STN and VIM region of interest (ROI) annotation accuracy for the subject device was validated using the same performance test protocol and acceptance criteria as the predicate OptimMRI (K230150). Results from the performance evaluation studies demonstrated that at least 90% of surface distances of inferior-lateral regions of VIM structure were not greater than 2.0mm compared to reference devices Guide XT (K213930) and SureTune4 (DEN210003).

Conclusions:

OptimMRI (v2) has the same indications for use and principles of operation as its predicate device. Design controls ensure that the minor differences between the subject and predicate device with the addition of the model for the VIM do not raise any new issues of safety and effectiveness when the device is used as labeled. Furthermore, performance data demonstrate that the functionality, output and clinical usage of OptimMRI (v2) is substantially equivalent to the predicate device. Therefore, it can be concluded that the OptimMRI (v2) is substantially equivalent to the previously cleared OptimMRI predicate device (K230150).