July 21, 2023

RebrAIn, SAS
% Ram Bedi
Consultant
Plateforme Technologique d'Innovation Biomédicale (PTIB)
Hôpital Xavier Arnozan
Avenue du Haut Lévêque
33600 Pessac, France

Re: K230150
Trade/Device Name: OptimMRI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: June 21, 2023
Received: June 21, 2023

Dear Ram Bedi:

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); 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230150

Device Name
OptimMRI

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.

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Chapter 6. 510(k) Summary

Submitter's Name:	RebrAIn, SAS
Address:	Plateforme Technologique d'Innovation Biomédicale (PTIB) Hôpital Xavier Arnozan Avenue du Haut Lévêque 33600 Pessac, France
Contact: Telephone:	Ram Bedi, PhD, MBA (425) 985 86780
Date:	January 17, 2023
Device/Trade Name:	OptimMRI
Common Name:	Medical Image Processing Software
Classification Name:	System, Image Processing, Radiological Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Code:	21 CFR 892.2050
Classification:	II
Product Code:	Primary: QIH Secondary: LLZ
Predicate Device:	K162830 – SIS Software, Surgical Information Sciences, Inc.

Device Description:

OptimMRI 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 anatomy to allow qualified medical

professionals to display, review, analyze, annotate, interpret, export, and plan neurosurgical functional procedures. OptimMRI is used as an aid to localize regions of the brain such as Subthalamic Nuclei (STN) and Ventral Intermediate Nucleus (VIM).

OptimMRI complies with the following standards:

ISO, 14971 Third Edition 2019-12, Medical devices – Application of Risk Management to medical devices

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 15223-1:2021, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1

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

IEC 62366-1:2015+AMD1:2020 Medical devices - Part 1: Application of usability engineering to medical devices + Amend. 1

ANSI UL 2900-1 Ed.1 2017 Standard for Software Cybersecurity Network-Connectable Products, Part I: 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.

Indications for Use:

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.

Comparison to Predicate Device

The OptimMRI software is substantially equivalent to the predicate that has already been cleared for USA distribution with 510(k) premarket notification number K162830. Briefly, the subject and predicate devices are based on the following same technological elements:

- Software tools for the visualization of DICOM compliant medical images
- Permit specialized annotation of anatomic structures using machine learning models
- Output data compatible with multiple surgical planning systems
- Support for 2D and 3D visualization tools
- Export of images and reports in DICOM format

The following technological differences exist between the subject and predicate device:

- Subject device is indicated for only pre-operative usage
- Segmentation process is semi-automatic for subject device compared to fully automatic for the predicate device
- Fusion imaging capability is not available in the subject device

- Region of interest is annotated with 3D crosses on the subject device compared to 3D segmented anatomical volumes on the predicate
- Localization of VIM region of interest is not available on the predicate device

Accuracy of segmentations for OptimMRI was compared to previously cleared commercially available comparable software tools. A total of 44 cerebral MRIs (88 hemispheres) were retrospectively annotated for the STN performance study, and 31 cerebral MRIs (62 hemispheres) were used for the VIM study. Qualified and experienced medical professionals performed the segmentation, and all validation criteria were met. The performance evaluation studies against reference devices Guide XT (K213930) and SureTune4 (DEN210003) demonstrated that at least 90% of surface distances of STN or VIM were not greater than 2.0mm when using segmentation tools for OptimMRI. The STN result is identical to the predicate SIS Software that used high-resolution 7T MRIs of the brain.

No new safety or efficacy issues were introduced by OptimMRI compared to the predicate device. There are no differences in indications for use between OptimMRI and the predicate SIS Software (K162830). Furthermore, performance data demonstrate that the functionality, output and clinical usage of OptimMRI is substantially equivalent to the predicate device.