December 6, 2024

Oxford Brain Diagnostics Ltd
% Yulia Nikova
Regulatory Affairs Manager
Ken Blocking Consulting LLC
3400 N Central Expy
Suite #110-225
Richardson, Texas 75080

Re: K240680
Trade/Device Name: CDM Insights
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 4, 2024
Received: November 5, 2024

Dear Yulia Nikova:

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,

Daniel M. Krainak, PhD
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)*
K240680

Device Name
CDM Insights

Indications for Use *(Describe)*
CDM Insights is a post-processing image analysis software that assists trained healthcare practitioners in viewing, analyzing, and evaluating MR brain images of adults > 45 years of age.

CDM Insights provides the following functionalities:

- Automated segmentation and quantitative analysis of individual brain structures and white matter hyperintensities
- Quantitative comparison of brain structures and derived values with normative data from a healthy population
- Presentation of results for reporting that includes numerical values as well as visualization of these results

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary for CDM Insights [K240680]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR §807.92.

Applicant/ Sponsor:	Oxford Brain Diagnostics Ltd The Oxford Centre for Innovation New Road, Oxford. OX1 1BY United Kingdom	
Contact Person:	Terry Pollard Chief Operating Officer TEL: +44 (0)1865 261400	
Date Prepared:	December 3rd, 2024	
Subject Device:	Manufacturer:	Oxford Brain Diagnostics Ltd
	Trade Name:	CDM Insights
	Product Name:	CDM Insights
	Classification Name:	Medical Image Management and Processing System
	Classification Panel:	Radiology
	Product Code:	QIH
	Regulation:	21 CFR §892.2050
	Class:	II
	Prescription or OTC Use:	Rx
Predicate Device:	Clearance:	K213706
	Clearance Date:	April 15, 2022
	Manufacturer:	Siemens Healthcare GmbH
	Trade Name:	AI-Rad Companion Brain MR
	Product Name:	AI-Rad Companion Brain MR
	Classification Name:	Medical Image Management and Processing System
	Classification Panel:	Radiology
	Product Code:	QIH
	Regulation:	21 CFR §892.2050
	Class:	II
	Prescription or OTC Use	Rx

Device Description:

CDM Insights is automated post-processing medical device software that is used by radiologists, neurologists, and other trained healthcare practitioners familiar with the post-processing of magnetic resonance images. It accepts DICOM images using supported protocols and performs: automatic segmentation and quantification of brain structures and lesions, automatic post-acquisition analysis of diffusion-weighted magnetic resonance imaging (DWI) data, and comparison of derived image metrics from multiple time-points.

The values for a given patient are compared against age-matched percentile data from a population of healthy reference subjects. White matter hyperintensities can be visualized and quantified by volume.
Output of the software provides numerical values and derived data as graphs and anatomical images with graphical color overlays.

510(k) Summary for CDM Insights [K240680]

CDM Insights output is provided in standard DICOM format as a DICOM-encapsulated PDF report.

Indications for Use:

CDM Insights is a post-processing image analysis software that assists trained healthcare practitioners in viewing, analyzing, and evaluating MR brain images of adults ≥ 45 years of age.

CDM Insights provides the following functionalities:

- Automated segmentation and quantitative analysis of individual brain structures and white matter hyperintensities
- Quantitative comparison of brain structures and derived values with normative data from a healthy population
- Presentation of results for reporting that includes numerical values as well as visualization of these results

Summary of Technological Characteristics:

The following aspects of the subject CDM Insights device and the predicate devices are identical:

- Intended Use
- Technological Principle
- Device Classification Name
- Classification Panel
- Regulation Number
- Product Code
- Classification
- Prescription Use

The Indications for Use and Intended Users for the CDM Insights device and the AI-Rad Companion Brain MR device use only slightly different wording:

- The CDM Insights devices refers to “healthcare practitioners” whereas the AI-Rad Companion Brain MR refers to “clinicians” in the Indications for Use and “healthcare professionals” in the Intended Users. We consider these to be equivalent.

In our Instructions for Use we have, in the same way as our primary predicate, clarified our definition of healthcare practitioners to include “radiologists, neurologists, and other trained healthcare practitioners familiar with the post-processing of magnetic resonance images”.

The following features are substantially equivalent between the CDM Insights device and the AI-Rad Companion Brain MRI device (the CDM Insights Device presents percentiles, whereas the AI-Rad Companion Brain MRI device presents z-scores):

- Brain Morphometry Segmentation
- Brain Morphometry Quantification
- Brain Morphometry: Deviation Map

510(k) Summary for CDM Insights [K240680]

	New Device	Predicate Device	Additional Predicate Device
Trade Name	CDM Insights	AI-Rad Companion Brain MR	OnQ Neuro
510(k) Submitter [Number]	Oxford Brain Diagnostics Ltd	Siemens Healthcare GmBh	CorTechs Labs, Inc
510(k) Number	K240680	K213706	K210831
Indications for Use	CDM Insights is a post-processing image analysis software that assists trained healthcare practitioners in viewing, analyzing, and evaluating MR brain images of adults ≥ 45 years of age. CDM Insights provides the following functionalities: - Automated segmentation and quantitative analysis of individual brain structures and white matter hyperintensities - Quantitative comparison of brain structures and derived values with normative data from a healthy population - Presentation of results for reporting that includes numerical values as well as visualization of these results	AI-Rad Companion Brain MR is a post- processing image analysis software that assists clinicians in viewing, analyzing, and evaluating MR brain images. AI-Rad Companion Brain MR provides the following functionalities: · Automatic segmentation and quantitative analysis of individual brain structures and white matter hyperintensities · Quantitative comparison of each brain structure with normative data from a healthy population · Presentation of results for reporting that includes all numerical values as well as visualization of these results	OnQ Neuro is a fully automated post-processing medical device software intended for analyzing and evaluating neurological MR image data. OnQ Neuro is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. OnQ Neuro is additionally intended to provide automatic fusion of derived parametric maps with anatomical MRI data. OnQ Neuro is intended for use on brain tumors, which are known/confirmed to be pathologically diagnosed cancer. OnQ Neuro is intended for comparison of derived image metrics from multiple time-points. The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.
Intended Users	The device is intended for healthcare practitioners familiar with the post-processing of magnetic resonance images	The device is intended for healthcare professionals familiar with the post processing of magnetic resonance images	Radiologists, Oncologists
Technological Principle	Software	Software	Software
Device Description	CDM Insights is automated post-processing medical device software that is used by radiologists, neurologists, and other trained healthcare practitioners familiar with the post-processing of magnetic resonance images. It accepts DICOM images using supported protocols and performs:	AI-Rad Companion Brain MR VA40 is an enhancement to the predicate, AI-Rad Companion Brain MR VA20 (K193290). Just as in the predicate, AI-Rad Companion Brain MR addresses the automatic quantification and visual assessment of the volumetric properties of various brain structures based on T1 MPRAGE datasets. In AI-	OnQ Neuro is a fully automated post-processing medical device software that is used by radiologists, oncologists, and other clinicians to assist with analysis and interpretation of neurological MR images. It accepts DICOM images using supported protocols and performs 1) automatic segmentation and volumetric quantification of brain tumors,

510(k) Summary for CDM Insights [K240680]

	New Device	Predicate Device	Additional Predicate Device
Trade Name	CDM Insights	AI-Rad Companion Brain MR	OnQ Neuro
	automatic segmentation and quantification of brain structures and lesions, automatic post-acquisition analysis of diffusion-weighted magnetic resonance imaging (DWI) data, and comparison of derived image metrics from multiple time-points. The values for a given patient are compared against age-matched percentile data from a population of healthy reference subjects. White matter hyperintensities can be visualized and quantified by volume. Output of the software provides numerical values and derived data as graphs and anatomical images with graphical color overlays. CDM Insights output is provided in standard DICOM format as a DICOM-encapsulated PDF report.	Rad Companion Brain MR VA40, the quantification and visual assessment extends to white matter hyperintensities on the basis of T1 MPRAGE and T2 weighted FLAIR datasets. These datasets are acquired as part of a typical head MR acquisition. The results are directly archived in PACS as this is the standard location for reading by radiologist. From a predefined list of 30 structures (e.g. Hippocampus, Left Frontal Grey Matter, etc.), volumetric properties are calculated as absolute and normalized volumes with respect to the total intercranial volume. The normalized values for a given patient are compared against age-matched mean and standard deviations obtained from a population of healthy reference subjects. The white matter hyperintensities can be visualized as a 3D overlay map and the quantification in count and volume as per 4 brain regions in the report. As an update to the previously cleared device, the following modifications have been made: 1. Modified Intended Use Statement 2. Addition of white matter hyperintensities overlay map, count and volume as per 4 brain regions 3. Enhanced DICOM Structured Report (DICOM SR) 4. Updated deployment structure	which are known/confirmed to be pathologically diagnosed cancer, 2) automatic post-acquisition analysis of diffusion-weighted magnetic resonance imaging (DWI) data and optional automated fusion of derived image data with anatomical MR images, and 3) comparison of derived image metrics from multiple time-points. Output of the software provides values as numerical volumes, and images of derived data as grayscale intensity maps and as graphical color overlays on top of the anatomical image. OnQ Neuro output is provided in standard DICOM format as image series and reports that can be displayed on most third-party commercial DICOM workstations
Brain Morphometry Segmentation	Pre-processing functionality for automatic segmentation and volumetry of T1-weighted	Pre-processing functionality for automatic segmentation and volumetry of MPRAGE data.	Software performs automatic segmentation

510(k) Summary for CDM Insights [K240680]

	New Device	Predicate Device	Additional Predicate Device
Trade Name	CDM Insights	AI-Rad Companion Brain MR	OnQ Neuro
	MRI data, e.g. MPRAGE or similar acquisition data.		
Brain Morphometry Quantification	Calculation of label maps (display of brain segmentation) and partially combined label maps (fused with the processed T1-weighted MRI data, e.g. MPRAGE or similar acquisition.	Calculation of label maps (display of brain segmentation) and partially combined label maps (fused with the processed MPRAGE data).	Software performs automatic quantification
Brain Morphometry: Deviation Map	Calculation of deviation map (representation of brain status in relation to reference data) and partially combined deviation maps (fused with the processed T1-weighted MRI data, e.g. MPRAGE or similar acquisition)	Calculation of deviation map (representation of brain status in relation to reference data) and partially combined deviation maps (fused with the processed MPRAGE data) User customizable color labels for the overlay map	Unknown
Diffusion Analysis	Yes, using a single-compartment diffusion model.	No	Yes, using single and multi-compartment diffusion models.
Support Longitudinal Analysis	Yes, performs comparison of derived image metrics from multiple time points	No	Yes, performs comparison of derived image metrics from multiple time points.
Brain White Matter Hyperintensities Segmentation	Pre-processing functionality for automatic segmentation and volumetry of T1-weighted data, that includes MPRAGE or similar acquisition, and FLAIR data. (volumetry of white matter hypointensities if FLAIR data is not available)	Pre-processing functionality for automatic segmentation and volumetry of MPRAGE and FLAIR data.	Information on White Matter Hyperintensities is not provided.
Brain White Matter Hyperintensities Quantification	Calculation of white matter hyperintensities volume (white matter hypointensities volume if FLAIR data is not available).	Calculation of white matter hyperintensities count and volume as per 4 brain regions.	Information on White Matter Hyperintensities is not provided.
Brain White Matter Hyperintensities Map	Calculation of white matter hyperintensities map fused with the processed FLAIR data (or white matter hypointensities map fused with the processed T1-weighted data). Color labels for the overlay map.	Calculation of white matter hyperintensities map fused with the processed FLAIR data User customizable color labels for the overlay map.	Information on White Matter Hyperintensities is not provided.

510(k) Summary for CDM Insights [K240680]

	New Device	Predicate Device	Additional Predicate Device
Trade Name	CDM Insights	AI-Rad Companion Brain MR	OnQ Neuro
Distribution & Archiving	Creation of an image series for a report. Automatic transfer of report to a PACS system.	Creation of an image series for a morphometry report. Automatic transfer of generated maps and morphometry report to a PACS system.	The software is configured at installation to receive input DICOM files from a network location, and output DICOM to a network destination.
User Interface Confirmation	No User Interface (UI)	Confirmation UI with basic visualization functionality	The software is designed without the need for a user interface after installation
User Interface Configuration	No User Interface (UI)	Configuration UI	The software is designed without the need for a user interface after installation
Architecture	Cloud solution	Cloud solution and Edge components deployed on customer premise.	Cloud solution or within a hospital's IT infrastructure on a server or PC-based workstation
Report Type	DICOM-encapsulated PDF report	DICOM structured report representation of a natural language report	Standard DICOM format as image series and reports
Physical Characteristics	CDM Insights is a medical device software package	AI-Rad Companion Brain MR VA40 is a medical device software package	The OnQ Neuro is a stand-alone medical device software package
Installation	Cloud	Server	Cloud or Server
Data Source	DICOM images using supported protocols	DICOM images using supported protocols	DICOM images using supported protocols

Summary of Non-Clinical Test Data:

Non-clinical tests were conducted to confirm the functionality of CDM Insights. Software validation and bench testing were conducted to assess the performance claims as well as the claim of substantial equivalence to the predicate device.

CDM Insights was developed to meet the requirements of multiple voluntary FDA Recognized Consensus Standards (i.e., ISO 13485, ISO 14971 and IEC 62304), as well as the FDA guidance document "Design Control Guidance for Medical Manufacturers." Non-clinical performance testing was conducted in compliance with IEC 62304, as well as the FDA guidance document "General Principles of Software Validation."

Software documentation has been provided for CDM Insights in compliance with the FDA guidance document "Content of Premarket Submissions for Device Software Functions" at the Basic Documentation Level, according to that guidance document. The documentation (including system-level software validation that included previously determined acceptance criteria) demonstrated conformance with FDA expectations for medical devices containing software functions. In addition, unit and integration testing was conducted during software development. Through these many activities, the CDM Insights Software Requirements Specifications were confirmed as being successfully executed in the developed and tested software, including mitigations as determined necessary through software risk management activities.

510(k) Summary for CDM Insights [K240680]

Cybersecurity documentation has been provided for CDM Insights in compliance with the FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions." Medical device cybersecurity activities for CDM Insights were conducted to meet the requirements of multiple voluntary FDA Recognized Consensus Standards (i.e., AAMI TIR57 and ANSI AAMI SW96), as well as the FDA guidance documents "Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software," "Postmarket Management of Cybersecurity in Medical Devices" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Performance testing of CDM Insights has been conducted to assess accuracy of image processing, run/rerun and scan/rescan repeatability of the underlying measurements, reproducibility across varying MRI scanner models and MRI protocols, statistical accuracy of percentiles of normative data. Each of these aspects of performance testing is summarized below.

Accuracy of segmentation for brain regions and for white matter hyperintensities, and accuracy of cortical surfaces, was tested against a gold standard of US board-certified neuroradiologists, using a total of 60 cases comprising a group of cognitively healthy individuals and a mix of individuals with disorders including Alzheimer's disease, mild cognitive impairment, frontotemporal dementia, and multiple sclerosis. Testing data included scans acquired on different scanner models, multiple manufacturers and at field-strengths of 1.5 and 3 tesla. White matter hyperintensities were automatically segmented with mean (standard deviation, SD) Dice overlap score of 0.66 (0.15), that exceeded the acceptance criterion of 0.58 taken from the primary predicate. For eight representative cortical regions, the mean (SD) Dice scores were as follows: Orbito-frontal 0.58 (0.10), Superior-frontal 0.72 (0.05), Sensorimotor 0.69 (0.14), Ventral-temporal 0.58 (0.05), Anterior-cingulate 0.60 (0.09), Precuneus 0.58 (0.08), Lateral-occipital 0.59 (0.11), Medial-occipital 0.63 (0.06). All regional mean Dice scores passed the acceptance threshold of 0.58. Visual ratings of segmentation quality and of cortical surface quality were typically rated by neuroradiologists as "good" or "excellent".

Repeatability was confirmed on a total of 121 healthy individuals with two or three repeated MRI scans. Reproducibility was tested with scans from over 1500 unique subjects (58% female) aged 45 to 90 years. Reproducibility was quantified across a range of MRI scanner model and protocol parameters.

Accuracy of percentiles was tested with almost 2000 test scans, independent of training scans used to derive percentiles. Information was available on race or ethnicity for the majority of individuals in both the training and test samples: more than 20% were non-white, and more than 5% were Hispanic. Data were obtained from 13 different source cohorts, 7 of which were based in the USA.

All performance tests were successfully passed in relation to pre-specified acceptance criteria, demonstrating safety and effectiveness substantially equivalent to the primary predicate.

Safety and Effectiveness:	The device labeling contains instructions for use and any necessary cautions and warnings to ensure safe and effective use of the device. Risk management is ensured via ISO 14971:2019 compliance to identify and provide mitigation of

potential risks in a risk analysis in the design phase and continuously throughout the development of the product. These risks are controlled via measures realized during software development, testing and product labeling, and risk control will continue throughout the life of the device.

Furthermore, the device is intended for healthcare practitioners familiar with the post-processing of magnetic resonance images.

The test results in this 510(k) premarket notification demonstrate that the CDM Insights: 1) complies with the international and FDA-recognized consensus standards and FDA guidance documents, as listed on the CDRH Premarket Review Submission Cover Sheet Form, and 2) meets the pre-defined acceptance criteria and is adequate for its intended use and specifications.

Conclusion: Oxford Brain Diagnostics considers CDM Insights to be substantially equivalent to the predicate device(s) listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.