November 20, 2020

ADM Diagnostics, Inc.
% Robin Martin
Co-Founder, Regulatory Strategist
Kinetic Compliance Solutions, LLC
PO Box 2134
MILWAUKEE WI 53201

Re: K193287
Trade/Device Name: CorInsights MRI
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 15, 2020
Received: October 19, 2020

Dear Robin Martin:

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,

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)*
K193287

Device Name
CorInsights MRI

Indications for Use *(Describe)*

The CorInsights MRI Medical Image Processing Software is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from MRI images. Volumetric measurements are compared to reference percentile data. CorInsights MRI is for adults age 45 to 95.

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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510(k) Summary K193287

Submission Date: November 18, 2020

Submitter Information:

Submitted By: Dawn Matthews, CEO
ADM Diagnostics, Inc.
555 Skokie Blvd; Suite 500
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Secondary Contact: Robin Martin
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Milwaukee, WI 53201

Device Information:

Trade Name: CorInsights MRI

Common Name: Medical Image Processing Software

Classification Name: System, Image Processing, Radiological, Picture archiving and communication system

Device Classification: 21 CFR 892.2050

Predicate Device(s): K170981 NeuroQuant
LLZ

Device Description: CorInsights MRI is a fully automated MR medical image processing software intended for automatic labeling, visualization and volumetric quantification of identifiable brain structures from DICOM formatted magnetic resonance images. The resulting output consists of a pdf report for review, which can be used in research and clinical use, and a DICOM image showing the anatomical structure boundaries identified by the software.

The proposed device provides morphometric measurements based on T1 MRI series. The output of this software only device includes morphometric reports that provide comparison of measured volumes to age and gender-matched reference data and an image volume that has been annotated with color overlays representing each segmented region.

	The architecture has a proprietary automated internal process that includes artifact correction, atlas-based segmentation, volume calculation, and report generation. Quality control measures include automated quality control including image header checks to verify that the scan acquisition protocol and provided data adhere to system requirements, an image morphometry check, a tissue contrast check, and value range checks.
Indications for Use:	The CorInsights MRI Medical Image Processing Software is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from MR images. Volumetric measurements are compared to reference percentile data. CorInsights MRI is intended for adults age 45 to 95.
Comparison to Predicate:	Functionally, both devices include the ability to automatically label, visualize and conduct volumetric quantification of segmentable brain structures from MR images. Performance testing outlined below demonstrated equivalent performance in segmentation accuracy and reproducibility compared to published predicate values. The predicate device indications include lesion analysis. The proposed CorInsights MRI does not. There is no significant impact to safety or efficacy based on this. Both systems are used by medical professionals, such as radiologists, neurologists and neuroradiologists, as well as by clinical researchers, as a support tool in assessment of structural MRIs. The proposed device employs the same fundamental scientific technology and the change in indications does not impact the intended use of the device.
Performance Testing:	No mandatory performance standards have been established for this device (Section 514 of the Act). The following testing was conducted / standards complied with to support the substantial equivalence of the proposed device to the predicate:

- Software testing was conducted to verify performance in accordance with FDA's guidance document entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

- In addition, the following standard was followed for DICOM Conformance: DICOM NEMA PS 3.1 - 3.20 (2016)
  Digital Imaging and Communications in Medicine (DICOM) Set

- Animal testing was not required to demonstrate substantial equivalence for the CorInsights MRI device.

- Performance Validation: The following performance data was analyzed to support substantial equivalence:

Category	Performance
Accuracy	CorInsights MRI hippocampal volume accuracy was tested using 80 subjects from the HaRP database as ground truth (Boccardi, et al.). • CorInsights MRI measured hippocampal volume with an IntraClass Correlation coefficient of 0.95 and a DICE coefficient of 83% left (standard deviation 2.5%) and 83% right (standard deviation 2.7%) and a mean absolute percentage difference of 6.2% left (standard deviation 4.4%) and 5.9% right (standard deviation 5.1%) as compared to ground truth volumes. CorInsights MRI cortical segmentation accuracy was tested using 80 subjects from a variety of databases with manual ground truth segmentation generated by neuroanatomy experts. • CorInsights MRI measured total gray volume with an IntraClass Correlation coefficient of 0.99, a DICE coefficient of 95% (standard deviation 1.6%), and a mean absolute percentage difference of 4.5% (standard deviation, 1.8%). • CorInsights MRI measured cortical subregions with DICE coefficients ranging from 81-93% and a mean absolute percentage difference range of 4.6% to 13.8% across all regions. CorInsights MRI Intracranial Volume (ICV) and ventricular accuracy were tested using an additional 70 subjects from a variety of databases with manual ground truth segmentation generated by neuroanatomy experts. • CorInsights MRI measured ICV with an IntraClass Correlation coefficient of 0.89, a DICE coefficient of 95% (standard deviation 1.1%) and a mean absolute percentage difference of 5.2% (standard deviation of 4.4%). • CorInsights MRI measured ventricular accuracy with an IntraClass Correlation coefficient of 0.98 (left and right), a DICE coefficient of 88% left (standard deviation 5.2%) and 87% right (standard deviation 5.6%) and a mean absolute percentage difference of 13.9% left (standard deviation

Category	Performance
	9.2%) and 15.2% right (standard deviation 9.9%) compared to ground truth volumes.
Reproducibility	In test-retest processing of two different scans from the same subject on the same scanner on the same day, CorInsights MRI measured volumes with an average IntraClass Correlation coefficient of 0.97, a DICE coefficient of 89% (standard deviation 4.0%) and a mean absolute percentage difference range of 0.7% to 5.8% with an average of 2.3% (standard deviation 2.7%) across all volumes listed in its report.
Normative Reference Database Development	The CorInsights MRI reference database was developed using T1 weighted MRI scans from 269 male and 331 female individuals of age 42 to 95 who were clinically diagnosed to be cognitively normal. In addition, these individuals were confirmed to be negative for amyloid pathology, and negative for a variety of other potential confounding abnormalities including overt vascular disease as evidenced by white matter lesions, stroke or tumor, normal pressure hydrocephalus, and with no history of traumatic brain injury or severe neuropsychiatric illness as documented with the data set or provided in the data set's inclusion criteria. This screening was performed to ensure that the CorInsights MRI reference represented normal values without potential influence by disease, even when asymptomatic.
Validation of Volume Measurement in Clinically Relevant Cases	Testing of CorInsights MRI included scans acquired from scanners with 1.5T and 3T field strengths, using accelerated and non-accelerated acquisition sequences, and representing a variety of scanner models from Siemens, GE, and Philips. Validation testing was conducted using patient scans from ages 45 to 95, with a broad spectrum of clinical diagnoses including cognitively normal, Mild Cognitive Impairment, typical and atypical Alzheimer's disease, and non-Alzheimer's dementias. Alzheimer's disease (AD) cases (confirmed for amyloid positivity) included late onset AD, Early Onset AD, Posterior Cortical Atrophy (PCA), Logopenic Progressive Aphasia, and Corticobasal Syndrome. Non-Alzheimer's cases included behavioral variant (bv) Frontotemporal Dementia (FTD), semantic variant (sv) FTD, Nonfluent Primary Progressive Aphasia, Primary Progressive Aphasia (other), amyloid negative Corticobasal Syndrome, vascular disease, moderate to severe white matter disease, and ventricular enlargement. Mild Cognitive Impairment (MCI) cases included early MCI, late MCI, and persons who converted to a clinical diagnosis of dementia at 12 months post-scan.

Category	Performance
	Volumes measured by CorInsights MRI were tested using normal subject scans, as well as data sets expected to have below normal gray tissue volumes or above normal ventricle volumes based upon well-established literature. These data sets included individuals with diagnoses of MCI, MCI who converted to a clinical diagnosis of AD at 12 months post-scan, late onset AD, Early Onset AD, bvFTD, svFTD, and PCA. CorInsights MRI values were compared to the percentile and z-score ranges expected based upon peer reviewed published literature for these data sets, and were confirmed to be in these ranges. Relationships between regions based on z-score ranking were also compared to published data and were in agreement with the literature. In all cases, the cognitively normal test group was confirmed not to differ from the normative reference group or reference values. In total, more than 1,400 scans from over 1,100 individuals were used in testing of CorInsights MRI.

Clinical: A clinical investigation was not required to demonstrate substantial equivalence to the predicate device.

Conclusion: The above testing supports that the proposed device is as safe, effective and performs as well as the legally marketed predicate in its intended use. Therefore, the proposed device is substantially equivalent to the predicate.