July 25, 2023

Imeka Solutions, Inc.
% Valerie Lacroix
Executive Vice President
195, Belvédère Nord #201
Sherbrooke, QC J1H 4A7
Canada

Re: K230913
Trade/Device Name: ANDI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: June 26, 2023
Received: June 27, 2023

Dear Valerie Lacroix:

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.

Submission Number *(if known)*

K230913

Device Name

ANDI

Indications for Use *(Describe)*

ANDI is intended for display of medical images and other healthcare data. It includes functions for image review, basic measurements, planning, and visualization (MPR reconstructions). Modules are available for image processing and atlas-assisted visualization and segmentation, where an output can be generated for use by a system capable of reading DICOM image sets.

ANDI is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white matter tracts. The information presented by ANDI is for measurement of brain white matter tracts only without making a prediction, diagnosis, or interpretation of brain health. It is the responsibility of the physician to review all clinical information associated with a patient in order to make a diagnosis and to determine next steps in the clinical care of the patient.

Typical users of ANDI are medical professionals, including but not limited to neurologists and radiologists. ANDI should be used only as adjunctive information. The decision made by trained medical professionals will be considered final. It is not a diagnostic aid.

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

Sponsor Information:
IMEKA Solutions, Inc.
195, Belvédère Nord
Sherbrooke, QC, Canada
J1H 4A

Contact Person	Valerie Lacroix Executive Vice President (888) 311-0599 valerie.lacroix@imeka.ca
Date of Summary:	March 31, 2023

Device Name and Classification

Common or Usual Name:	Automated Radiological Image Processing Software
Proprietary Name:	ANDI
Classification Name:	System, Image Processing, Radiological Picture Archiving and Communications System (21 CFR § 892.2050)
Classification Product Code:	QIH, LLZ
Predicate Device:	Quicktome (K203518)

Description of Device
ANDI is quantitative imaging software that extracts features from medical images to provide adjunctive information for use with the complete standard of care evaluation of the patient. The device processes diffusion weighted images using local (on a per-voxel basis) and global (for the whole brain) reconstruction algorithms, respectively called modeling, tractography, and white matter bundling, to map microstructural properties of the white matter. ANDI achieves its intended use by extracting white matter bundles that connect specific regions of the brain and then performing a microstructure analysis along those bundles.

ANDI combines two families of features derived from diffusion Magnetic Resonance Imaging (dMRI) along with T1-weighted images as an auxiliary input to augment processing. T1-weighted imaging is a general imaging modality that highlights differences in tissue types (skull, cerebrospinal fluid, white / gray matter), whereas dMRI is sensitive to the direction of white matter structures, based on the movements of water protons. Combining information from these MRI types gives ANDI data needed to quantify and visualize local water diffusion properties and to map these microstructural properties of the white matter along specific white matter bundles.

The ANDI analysis techniques provide quantitative insight into white matter microstructure,

corresponding to the local environment of each neurological fiber population. The resulting report provides trained medical professionals with reference information as an adjunct to care. The information included in the report is intended to be used by the trained medical professionals as a comparison between a patient and a control population as well as a comparison to the subject himself, with an optional longitudinal comparison.

Indications for Use

ANDI is intended for display of medical images and other healthcare data. It includes functions for image review, basic measurements, planning, and visualization (MPR reconstructions). Modules are available for image processing and atlas-assisted visualization and segmentation, where an output can be generated for use by a system capable of reading DICOM image sets.

ANDI is indicated for use in the processing of diffusion-weighted MRI sequences into 3D maps that represent white matter tracts. The information presented by ANDI is for measurement of brain white matter tracts only without making a prediction, diagnosis, or interpretation of brain health. It is the responsibility of the physician to review all clinical information associated with a patient in order to make a diagnosis and to determine next steps in the clinical care of the patient.

Typical users of ANDI are medical professionals, including but not limited to neurologists and radiologists. ANDI should be used only as adjunctive information. The decision made by trained medical professionals will be considered final. It is not a diagnostic aid.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device

Information provided in this 510(k) submission shows that ANDI is substantially equivalent to the predicate device, Quicktome, cleared under K203518, in terms of intended use, indications for use, physical characteristics, workflow, anatomical location, and technological characteristics.

Both devices are cloud-based image processing software that apply an algorithm for modeling diffusion data and generating tractography (whole brain CSD tractography) reports for clinicians to use in planning and visualization. Both devices accept similar inputs, T1 and multi-directional diffusion weighted images (DWI), to process MRI information and output a report using CSD as the underlying diffusion modeling technique used by a tractography process to reconstruct white matter pathways. The output of both devices is intended as adjunctive information for medical professionals.

While both devices share many characteristics, there are identified differences, none of which have a negative impact on the device safety or effectiveness, nor do they raise any potential safety risks:

- The predicate utilizes the Glasser atlas, which applies surfacic definitions delineating 180 areas per hemisphere bounded by sharp changes in cortical architecture, function, connectivity, and/or topography. In contrast, ANDI uses a proprietary white matter bundles atlas defined by 3D models to segment the major white matter pathways from the subject's tractogram. The differences in the atlas types are minimal, with both approaches used to identify white matter bundles.
- The predicate device accepts T1, T2, FLAIR, and DWI images. The subject device does not accept T2 or FLAIR images because the subject device does not generate endpoints from T2 or

FLAIR images. Likewise, ANDI accepts reversed-phase encoded B=0 image as an optional input. This difference in input format does not present concerns for safety or effectiveness given that the main information source for both devices is the DWI, and the T1, T2, or FLAIR images are auxiliary images used to augment the quality of processing. Given that the subject device uses a robust T1-based refinement of processing, there is no performance impact in not supporting T2 or FLAIR.

- Output data for the two devices are similar, however the output format between the two devices is different. The predicate device outputs a DICOM Structured Report, while the subject device output is a DICOM encapsulated PDF report. This difference does not raise concerns for safety or effectiveness because both are DICOM-compliant files that are supported by RIS/PACS and both formats can contain the same information.
- While the predicate features a user interface for planning and visualization, ANDI relies on an API for image input and report output. This difference does not present a safety or efficacy concern because the output is sent to the RIS/PACS in a DICOM-compliant format.
- The predicate device uses the DICOM format for its input. The subject device uses the NIfTI file format for its input. This difference does not present a safety or effectiveness concern because the image data in both formats is identical.

Comparisons to the Predicate device in conjunction with design verification and validation activities described in the 510(k) submission support substantial equivalence of ANDI.

Non-Clinical Test Summary
Non-clinical performance testing has been performed in compliance with the following International and FDA recognized consensus standards and FDA guidance document:

- ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices
- ANSI/AAMI/IEC 62304:2006/A1:2016, Medical Device Software - Software Life Cycle Processes
- Digital Imaging and Communications in Medicine (DICOM) Set (NEMA PS 3.1 - 3.20)
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, November 2021

Performance tests were conducted to assess the measured end points, AI-based brain extraction, and robustness of the processing pipeline. A summative evaluation was performed to assess the content and structure of the ANDI report.

Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to formalize after ensuring that the software fully satisfies all expected and previously defined system requirements and features.

Through the performance test, it was confirmed that ANDI meets all performance test criteria and that all functions work as intended. Test results support the conclusion that device performance satisfies the design intent and is equivalent to its predicate device.

Clinical Test Summary
No clinical studies were considered necessary and performed.

Conclusion

In conclusion, the tests conducted, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of ANDI meet applicable requirements and standards for the safety and effectiveness of the device for its intended use. There are differences in technological characteristics between the predicates and the proposed device, but the nature of those differences do not raise new or different questions of safety or effectiveness as compared to the predicate devices. Therefore, ANDI is substantially equivalent to the currently marketed predicate device.