



October 22, 2025

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

Re: K252298

Trade/Device Name: ANDI 2.0  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical image management and processing system  
Regulatory Class: Class II  
Product Code: QIH, LLZ  
Dated: July 23, 2025  
Received: September 30, 2025

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 (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](mailto: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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252298

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Please provide the device trade name(s).

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ANDI 2.0

Please provide your Indications for Use below.

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ANDI is intended for the display of medical images and other healthcare data. It includes functions for processing MR images, atlas-assisted visualization, segmentation, and volumetric quantification of segmentable brain structures. The output is generated for use by a system capable of reading DICOM image sets.

The information presented by ANDI does not provide prediction, diagnosis, or interpretation of brain health. Clinical interpretation and decision-making are the responsibility of the physician, who must review all clinical information associated with a patient in order to make a diagnosis and to determine the 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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

## 510(k) Summary

### Sponsor Information:

IMEKA Solutions, Inc.  
195, Belvédère Nord  
Sherbrooke, QC, Canada  
J1H 4A7

Contact Person: Valerie Lacroix  
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(888) 311-0599  
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Date of Summary: September 26, 2025

### Device Name and Classification

Common or Usual Name: Automated Radiological Image Processing Software  
Proprietary Name: ANDI 2.0  
Classification Name: System, Image Processing, Radiological Picture Archiving and Communications System (21 CFR § 892.2050)  
Classification Product Code: QIH, LLZ  
Predicate Device: ANDI (K230913)  
Reference Device: Neurophet AQUA (K220437)

### Description of Device

ANDI is software as a medical device (SaMD) that can be deployed on a cloud-based system, or installed on-premises. It is delivered as software as a service (SaaS) and operates without a graphical user interface. The software can be used to perform DICOM image viewing, image processing, and analysis, specifically designed to analyze brain MRI data. It processes diffusion-weighted and T1-weighted images to quantify and visualize white matter microstructure, providing adjunctive information to aid clinical evaluation. An optional AI-based segmentation feature enables quantification of the volume of gray matter regions. The results are output in a report that presents reference information to assist trained medical professionals in clinical decision-making by enabling comparisons between a patient's data, a normative database, and the patient's longitudinal data.

### Indications for Use

ANDI is intended for the display of medical images and other healthcare data. It includes functions for processing MR images, atlas-assisted visualization, segmentation, and volumetric quantification of segmentable brain structures. The output is generated for use by a system capable of reading DICOM image sets.

The information presented by ANDI does not provide prediction, diagnosis, or interpretation of brain health. Clinical interpretation and decision-making are the responsibility of the physician, who must review all clinical information associated with a patient in order to make a diagnosis and to determine the 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.

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

The subject device is a modified version of the predicate device that introduces technological enhancements, including an optional AI-based method to enhance segmentation and additional quantification outputs. Despite these updates, the subject and predicate devices remain substantially equivalent in terms of intended use, general functionality, and technological characteristics.

Information provided in this 510(k) submission shows that ANDI is substantially equivalent to the predicate device, cleared under K230913, in terms of intended use, indications for use, physical characteristics, workflow, anatomical location, and technological characteristics.

While the subject device incorporates minor technical enhancements compared to the predicate device, these differences do not affect the intended use or indications and do not introduce new or increased clinical risks.

- **Volumetric Grey Matter Quantification:** The subject device provides volumetric quantification of segmented grey matter as part of its report output. While the predicate device performs grey matter segmentation, it does not present grey matter volume as a reportable output. This enhancement is a minor technical variation that does not alter the clinical function or risk profile of the device.
- **Expanded Normative Database Comparison:** Both devices compare outputs against a control population (normative reference). In addition to the white matter measures of the predicate device, the subject device's normative reference includes cortical and subcortical brain structures volumes. All measures included in the normative reference are derived from the same source. This represents an extension of an existing functionality that does not impact the device's intended use or safety when compared to the predicate device. Comparative studies demonstrate that the expanded normative reference maintains equivalent performance to the predicate device while providing enhanced clinical information through additional brain structure measurements.
- **Use of AI for Grey Matter Segmentation:** While both devices utilize intensity-based segmentation for white matter, grey matter, and CSF, the subject device employs an AI algorithm for grey matter segmentation to support volumetric quantification. This is the most notable difference, yet it does not alter the device's intended use or raise new safety concerns. The potential risk remains dependent on segmentation performance, and performance testing of the proposed device achieves accurate and reproducible results. This feature has been evaluated by comparison to a reference device (Neurophet AQUA v2, K220437) to validate the performance of the output segmentation for the subject device using the same methodology as the reference device.

Comparative analyses between the subject and predicate devices, including detailed assessments of intended use, technological characteristics, and performance specifications, have been conducted as part

of this 510(k) submission. These comparisons, together with the results from design verification and validation activities, including bench testing, software validation, and risk analysis, demonstrate that the subject device performs as intended and does not raise new questions of safety or effectiveness. Collectively, the evidence supports the substantial equivalence of the subject device to the predicate device.

### **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 Device Software Functions, June 2023
- Guidance for Industry and FDA Staff – Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 2023

Performance testing was conducted to evaluate key endpoints, including the accuracy of the AI-based brain extraction, the accuracy and robustness of the brain regions segmentation and the overall robustness of the processing pipeline. A summative evaluation was also performed to assess the completeness, clarity, and structure of the output report.

### AI / ML module development

The device incorporates a pretrained third-party brain segmentation algorithm as detailed in the SBOM. The algorithm was subjected to training using 140 representative subjects from 3 MRI manufacturers. Validation data included 747 independent subjects from multiple sites and MRI manufacturers. All subjects were selected a priori and secluded in a separate dataset to avoid any contamination.

### AI / ML performance data

Performance testing of the brain segmentation algorithm as integrated in the ANDI device was performed on images preprocessed by ANDI, ensuring data independence since ANDI-preprocessed images were not available for the training of the algorithm by the third-party algorithm.

The accuracy and robustness of the brain regions segmentation was evaluated using a total of 71 subjects representative of USA population (n=35 females; n=36 males; age range 18-86 yo; n=38 USA origin), including healthy (n=35) and diseased subjects (Multiple Sclerosis (n=11); Parkinson’s disease (n=12); Alzheimer’s disease (n=12); mild cognitive impairment (n=1)). Results stratified by age, gender, pathology, MRI manufacturer and field strength were also provided. The reproducibility of the brain regions segmentation was evaluated using 2 timepoints from 59 subjects (n=30 females; n=29 males; age range 23-86 yo; n=38 USA origin). Only healthy subjects were selected for the reproducibility assessment to avoid any bias from disease progression. The brain segmentation performance testing datasets included MPRAGE images acquired on a variety of MRI scanner models from the three main manufacturers (GE, Philips and Siemens).

To constitute a ground truth of brain segmentations, 71 preprocessed T1 images were pre-segmented using Freesurfer v7.4.1. The resulting segmentations were then manually corrected by an expert and approved by a panel of 3 board certified neuroradiologists. Dice coefficients were computed between

ANDI 2.0's brain regions segmentation and the expert approved ground truth to assess the accuracy and robustness. Average Dice coefficients ranged from 0.89 to 0.96 for major subcortical brain structures and from 0.79 to 0.93 for major cortical brain structures, which are higher than their respective acceptance criteria of  $\geq 0.75$  and  $\geq 0.8$ .

The reproducibility of brain region segmentation was evaluated by calculating absolute volume differences between two scanning timepoints for identical subjects. Analysis of major cortical and subcortical brain structures yielded a mean absolute volume difference of 2.1%, with individual structures ranging from 1.2% to 3.9%. These findings satisfy the predetermined acceptance criterion of maximum absolute volume difference below 7%, thereby confirming adequate reproducibility of the segmentation methodology for clinical application.

Software verification and validation activities were carried out in accordance with pre-defined test protocols, established prior to testing. All test results were reviewed and approved by qualified technical personnel to confirm that the software meets all specified system requirements and functional expectations before proceeding to finalization.

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 does 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.