



May 28, 2026

IMEKA Solutions, Inc.
% Kory Dillman
Director, Global Regulatory Consulting
Eversana
7045 College Blvd.
Overland Park, Kansas 66211

Re: K261405

Trade/Device Name: ANDI 2.2
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 29, 2026
Received: April 29, 2026

Dear Kory Dillman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

A handwritten signature in black ink, appearing to read 'DK', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

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.

K261405

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Please provide the device trade name(s).

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ANDI 2.2

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 ([21 CFR 801 Subpart D](#))
☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
☐ Infants (29 days old to < 2 years old)
☐ Children (2 years old to < 12 years old)
☒ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

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510(k) Summary

K261405

Special 510(k) Premarket Notification
ANDI 2.2 (Modification to ANDI 2.0)

Sponsor Information:

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

Contact Person	Valerie Lacroix Executive Vice President (888) 311-059920 valerie.lacroix@imeka.ca
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Date of Summary: April 27, 2026

Device Name and Classification

Common or Usual Name:	Automated Radiological Image Processing Software
Proprietary Name:	ANDI 2.2
Regulation Name:	Medical image management and processing system (21 CFR § 892.2050)
Classification Product Code:	QIH, LLZ
Predicate Device:	ANDI 2.0 (K252298)

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 has the same fundamental scientific technology as the predicate device. Both devices:

- Process diffusion-weighted MRI data to generate white matter tract representations
- Provide quantitative measurements and visualization outputs
- Compare outputs against a normative reference dataset
- Utilize a deterministic processing pipeline
- Use artificial intelligence for skull stripping as a pre-processing function

The subject device differs from the predicate device by expanding the normative reference dataset to include additional subjects, extending the lower bound of the dataset to include subjects aged 16-17 years.

This modification does not alter the device's processing steps, algorithms, or output characteristics.

Performance Data

Performance testing, risk analysis, and literature review were conducted to evaluate the modification.

- **Performance Testing:** Demonstrated that device outputs, including application of the normative reference, maintain equivalent performance compared to the predicate device.
- **Risk Analysis:** Identified no new hazards associated with the modification. One risk showed an increased probability in the expanded population; however, existing mitigations remain effective and maintain acceptable residual risk.
- **Literature Support:** Supports the applicability of normative comparisons across the expanded age range.

Performance acceptance criteria are based on measures derived from underlying white matter characteristics and are not dependent on disease state. Evaluation demonstrated no clinically meaningful differences compared to adult populations.

Clinical Test Summary

No clinical studies were considered necessary and performed.

Substantial Equivalence Summary

The subject device is substantially equivalent to the predicate device (ANDI 2.0; K252298).

The modification consists of an expansion of the normative reference dataset to include additional subjects, extending the lower bound of the dataset to include subjects aged 16-17 years. This represents an extension of existing functionality and does not affect the intended use, technological characteristics, or overall performance of the device.

The evidence provided demonstrates that the modification does not introduce new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.