October 22, 2024

NordicNeurolab AS
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K243209
Trade/Device Name: nordicMEDiVA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 1, 2024
Received: October 1, 2024

Dear Prithul Bom:

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, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243209

Device Name

nordicMEDiVA

Indications for Use *(Describe)*

Intended use
The nordicMEDiVA software is an advanced visualization and processing platform with a specific focus on providing algorithms designed to analyze functional and dynamic MRI data of the brain. The software runs on a server in a networked environment and is accessed by users via a standard web browser. It can communicate with other imaging platforms that support DICOM, and process medical image data acquired through DICOM-compliant imaging devices and modalities.

Intended users
nordicMEDiVA must be operated according to its intended purpose and only by qualified medical personnel with the necessary knowledge in accordance with country-specific regulations, such as trained radiological technicians or physicians. Users must have received training in applicable areas, such as in MR technology and neuroanatomy.

Indications for use
nordicMEDiVA is indicated for image analysis and visualization of functional and dynamic MRI data of the brain, presenting derived properties and parameters from the input image data in a clinically useful context.

Contraindications
The software is not be used as an archiving device for patients' image data.

The software is not to be used as a sole basis for clinical decisions, but further evidence has to be taken into account.

The software is not to be used as a sole basis in emergency care applications.

The software is not to be used for applications other than the analysis and visualization of MR data, or data derived thereof, of the human brain.

Patient target population
nordicMEDiVA has no limitation concerning the patient population.

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.

510(k) #: K243209

510(k) Summary

Prepared on: 2024-09-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	NordicNeuroLab AS
Applicant Address	Mollendalsveien 1 Bergen 5009 Norway
Applicant Contact Telephone	+47 55 70 70 95
Applicant Contact	Mrs. Chandana Gurung Bhandari
Applicant Contact Email	chandana@nordicneurolab.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	nordicMEDiVA
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K163324	nordicBrainEx	LLZ
K241608	nordicMEDiVA	LLZ
K203518	Quicktome	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

nordicMEDiVA is a software as a medical device (SaMD) for processing of MR images of the brain. Users will configure analysis pipelines, which are executed automatically when image data is received or manually by a user. The user can choose to send the results to other DICOM nodes for review or use nordicView for their review and export the results to PACS, neuro navigation systems, or other DICOM-compliant modalities.

nordicMEDiVA is a server-client solution and can be installed on a local server at the customer's location or in a cloud-based setup. The software is containerized with Docker technology and operates on a GPU-enabled Linux host. This allows customers to manage the server environment themselves or use it as a Software as a Service (SaaS) hosted by NordicImagingLab AS in the cloud. Customers can install the server on physical hardware or in their own cloud infrastructure.

The device comprises a database, DICOM functionality, various APIs, a visualization engine, and medical image analysis modules. The device is not intended for long-term persistent storage of medical diagnostic data.

The device incorporates rule-based algorithms for the calculation of metrics from dynamic MRI data. The device does not incorporate AI algorithms based on neural networks.

The device connects to other imaging modalities, such as MR scanners, PACS, and surgical navigation systems.

The following modules provide the main functions of the device.

Viewer: A browser-based user interface, accessed from desktop clients, that provides tools for general image visualization, export, and relevant analysis tools for BOLD-fMRI, diffusion MRI (including tractography), and DSC-perfusion.

Task-based fMRI: BOLD task-based fMRI analysis highlights small magnetic susceptibility changes in the human brain in areas with altered blood flow resulting from neuronal activity. The image processing requires the definition of a so-called design matrix which is used to calculate voxel-wise statistics conveying information about the probability of the voxel being involved in the execution of the given task.

The design matrix is is defined such that the timing corresponds to the task or stimulation that was presented to the patient during the scan. The task or stimulation presented during scan time is often refered to as “the paradigm”. The design matrix can be defined manually by the user, or a paradigm from nordicAktiva - another product from NordicNeuroLab - can be used.

nordicAktiva is a software, marketed by NordicNeuroLab, that may be used during scan time to present the paradigm to the patient or subject being scanned. The use of nordicAktiva is not required.

Diffusion and tractography: The analysis of diffusion-weighted MRI data can be used to model water diffusion properties in the brain's white matter. In addition to the calculation of diffusion tensor imaging (DTI) derived maps such as fractional anisotropy (FA) and mean diffusivity (MD), tractography can be performed to create 3D reconstructions of the major white matter pathways. Both DTI and spherical deconvolution (SD) models are available for fiber tracking. Unlike DTI, the SD model can resolve multiple fiber populations at each voxel so can track through crossing fiber regions to give more accurate representations of white matter anatomy.

DSC: Calculations of perfusion-related parameters that provide information about the blood vessel structure and characteristics. Such maps include blood volume, blood flow, time to peak, mean transit time, and leakage.

Platform: The platform includes a database, DICOM functionality, various APIs, processing pipelines for the medical image analysis modules. Serves as a backbone component for the other modules of nordicMEDiVA.

Dashboard: a browser-based user interface accessed from desktop clients for administration and configuration.Reference to previous and similar generations of the product

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Intended use
The nordicMEDiVA software is an advanced visualization and processing platform with a specific focus on providing algorithms designed to analyze functional and dynamic MRI data of the brain. The software runs on a server in a networked environment and is accessed by users via a standard web browser. It can communicate with other imaging platforms that support DICOM, and process medical image data acquired through DICOM-compliant imaging devices and modalities.

Intended users
nordicMEDiVA must be operated according to its intended purpose and only by qualified medical personnel with the necessary knowledge in accordance with country-specific regulations, such as trained radiological technicians or physicians. Users must have received training in applicable areas, such as in MR technology and neuroanatomy.

Indications for use
nordicMEDiVA is indicated for image analysis and visualization of functional and dynamic MRI data of the brain, presenting derived properties and parameters from the input image data in a clinically useful context.

Contraindications
The software is not be used as an archiving device for patients' image data.

The software is not to be used as a sole basis for clinical decisions, but further evidence has to be taken into account.

The software is not to be used as a sole basis in emergency care applications.

The software is not to be used for applications other than the analysis and visualization of MR data, or data derived thereof, of the human brain.

Patient target population
nordicMEDiVA has no limitation concerning the patient population.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The primary medical purpose conveyed in the intended use of both the predicates and the subject device is the same.

Although the wording of the intended use statements is slightly different from the predicate devices, the primary intention is the same. Both the subject, the predicate device and reference devices combined enable dynamic susceptibility contrast-enhanced (DSC)-, BOLD- and diffusion-weighted magnetic resonance imaging (MRI) data analysis, presenting the derived properties and parameters in a clinically valuable context. We identified no difference in the intended use statements that impacts the safety and effectiveness of the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

nordicMEDiVA has the same technological characteristics as the predicate device nordicBrainEx (K163324). Both the subject device and the predicate device:

- Allow for the import and export of MR DICOM images from other DICOM-compliant imaging devices such as MR scanner, PACS and surgical navigation systems.
- Has a graphical user interface for the clinical evaluation of analysis results.
- Allow for co-registration of dynamic and functional MRI data to structural MRI data.
- Allow for region of interest analysis (ROI), distance measurements, and the export of these measurements to PACS.
- Allow for the generation of secondary data for use in surgical navigation systems.
- Contain analysis modules for DSC-, Diffusion- and BOLD fMRI image processing.

The subject device differs from the predicate device in its technological characteristics in that:
- The subject device is a thin client application deployed in a server environment, and the graphical user interface is accessed via a web browser. The predicate device is a desktop (thick client) application.
- The subject device contains user-defined automation rules for automated image data analysis, while in the predicate device, a user has to initiate image analysis manually.

The DSC- and BOLD fMRI analysis of the subject device has technological characteristics identical to those of the reference device, nordicMEDiVA (K241608).

These differences do not raise additional questions about the safety or effectiveness of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical performance testing has been performed on the nordicMEDiVA software and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software – Software life cycle processes
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 82304-1 Health software – Part 1: General requirements for product safety

nordicMEDiVA was tested in accordance with verification and validation processes. Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.

Formative and summative usability studies have been performed with users from the intended audience.

The test results are summarized below:

- All scenarios from the summative usability test met the acceptance criteria completely, no new risks were found and existing risk control measures were proven to be effective.
- The results from Diffusion and Tractography were evaluated in comparison with equivalent results from the predicate device, nordicBrainEx (K163324). The results were reviewed by internal and external clinical experts and proven to be as effective as the predicate device
- The results from BOLD fMRI were evaluated in comparison with equivalent results from the predicate device, nordicBrainEx (K163324). The results were reviewed by internal and external clinical experts and proven to be as effective as the predicate device
- The results from the DSC was confirmed to be the same as the reference device nordicMEDiVA (K241608) where a Lin's Concordance Correlation Coefficient of enhancing voxels was calculated with acceptance criteria being greater than or equal to 0.8 was applied.

Cybersecurity considerations related to nordicMEDiVA are included within this submission. nordicMEDiVA conforms to cybersecurity requirements by implementing a means to prevent unauthorized access, modification, misuse, denial of use or unauthorized use of information stored, accessed or transferred from a medical device to an external recipient.

We believe that nordicMEDiVA is as safe and effective as the identified predicate devices and does not introduce new safety and effectiveness concerns.