NordicNeuroLab AS
% Chandana Gurung Bhandari
VP Quality
Moellendalsveien 1
Bergen, Vestland N-5009
NORWAY

March 3, 2022

Re: K212720
Trade/Device Name: nordicDSC
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 18, 2022
Received: January 21, 2022

Dear Chandana Gurung Bhandari:

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,

For

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)*
K212720

Device Name
nordicDSC

Indications for Use *(Describe)*

nordicDSC is a medical image post-processing software for the analysis of the dynamic time course of the dynamic susceptibility contrast (DSC) enhanced MR data of the human brain to be used by trained professionals such as physicians, radiologists, and medical technicians to yield information useful in clinical applications.

The software is intended to be used off-line and in combination with a DICOM handling platform that can allow for user interactions, sending, receiving, and viewing of data, data quality control, and connection to network.

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) Summary
NordicNeuroLab AS
nordicDSC Software

Submitter: NordicNeuroLab AS
Møllendalsveien 1
N-5009 Bergen
Norway
Phone: +47 55 70 70 95

Primary Contact: Chandana Gurung Bhandari (chandana@nordicneurolab.com)

Proprietary Name:	nordicDSC Software
Device:	System, image processing, radiological
Classification Name:	Medical image management and process system
Classification Regulation:	892.2050
Class:	II
Panel:	Radiology
Product Code:	LLZ
Predicate device name:	Nordic Image Control and Evaluation (nordicICE) Software (K090546)

Device Description

nordicDSC is an image analysis module that can be integrated into hospital infrastructure to analyze dynamic susceptibility contrast-enhanced (DSC) perfusion data obtained from Magnetic Resonance Imaging (MRI). The product can be deployed as a plugin to a DICOM handling platform.

The program functionality can be divided into three main categories:

1. Accessing image data

2. MR image processing and analysis

3. Generating output, including information regarding blood volume, blood flow, time to peak, and leakage.

Intended Use

nordicDSC is a medical image post-processing software. The software is intended for the analysis of the dynamic time course of the dynamic susceptibility contrast (DSC) enhanced MR data of the human brain and to generate parametric maps including, but not limited to, blood volume, blood flow, time-to-peak, and vascular leakage.

The software is intended to be used off-line and in combination with a DICOM handling platform that can allow for user interactions, sending, receiving, and viewing of data, data quality control, and network connection. The output of nordicDSC is intended to be interpreted by trained professionals such as physicians, radiologists, and medical technicians to yield information useful in clinical applications.

Indications for Use

nordicDSC is a medical image post-processing software for the analysis of the dynamic time course of the dynamic susceptibility contrast (DSC) enhanced MR data of the human brain to be used by trained professionals such as physicians, radiologists, and medical technicians to yield information useful in clinical applications.

The software is intended to be used off-line and in combination with a DICOM handling platform that can allow for user interactions, sending, receiving, and viewing of data, data quality control, and connection to network.

Technological Characteristics and Substantial Equivalence

The nordicDSC software is substantially equivalent to the previously cleared Nordic Image Control and Evaluation (nordicICE) software, with the premarket clearance K090546. A short side-by-side comparison of the fundamental characteristics of nordicDSC and nordicICE is provided in the table below.

Feature	nordicDSC	nordicICE	Comment
Development framework	C++, CMake	Embarcadero C++ Builder 2010	
Programming language	C++	C++	
Operating environment	Cross-platform, is run as plugin to a DICOM handling platform	"Off-the-shelf" windows PC workstation	
Input data	DICOM compliant MR data: T2* weighted dynamic susceptibility contrast-enhanced data sets	DICOM compliant MR data: T2* weighted dynamic susceptibility contrast-enhanced data sets	
Dynamic analysis	Dynamic susceptibility contrast (DSC) MR perfusion	Dynamic susceptibility contrast (DSC) MR perfusion	
Fully automatic processing	Yes	No	
Automatic motion correction	Yes	Yes	
Visualization of results	No	Yes	
Reading of DICOM data	Yes	Yes	
Saving of DICOM data	Yes	Yes	
Sending of DICOM data	No	Yes	

Leakage correction	Yes (2 methods)	Yes (2 methods)	Same methods in both devices
CBV map	Yes	Yes	
CBF map	Yes	Yes	
Tmax map	Yes	Yes (called "Delay map")	
TTP map	Yes	Yes	
Leakage map	Yes	Yes	
Automatic AIF detection	Yes (global unsupervised search)	Yes (supervised search from user selected slice)	Quality control of AIF is advised
Manual AIF selection	No	Yes	
Predefined AIF	Yes	Yes	Same selection in both devices
Vessel segmentation	Yes	Yes	
Provide graph output for user inspection	Yes	Yes	For example, AIF curve and Delta R2* curve

The rationale for determining the substantial equivalence between nordicDSC and nordicICE is based on the defined intended use, indications for use, and the technical and operational characteristics of the two applications. To verify that nordicDSC fulfils the defined characteristics and requirements, it has been subject to extensive in-house testing. The successful completion of said tests verifies the claimed characteristics of nordicDSC, and thus supports the determination of substantial equivalence.

Brief discussion of the nonclinical tests submitted, referenced, or relied on

Non-clinical performance testing has been performed on the nordicDSC 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 Edition 1.0 2016-10 Health software – Part 1: General requirements for product safety

The nordicDSC Software 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. The algorithm is inherently nondeterministic, so head-to-head comparisons have to consider the internal variation, which has been found to be within +/- 10%.

The test results in this 510(k)premarket notification demonstrates that nordicDSC:

- Complies with the international and FDA-recognized consensus standards and FDA guidance document, and
- Meets the acceptance criteria and is adequate for its intended use and specifications.

Overall conclusion

The nordicDSC Software is substantially equivalent to the identified predicate device, nordicICE Software (K090546)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, verification and validation testing demonstrate the safety and efficacy of the device to meet its intended use and specifications.

NordicNeuroLab AS believes that the proposed device, nordicDSC Software, is substantially equivalent to its identified predicate device and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.