K123306

MAY 20 2013

510(k) Summary
NordicNeuroLab AS
nordicTumorEx Software

Submitter: NordicNeuroLab AS
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Primary Contact: Chandana Gurung Bhandari (Chandana@nordicneurolab.com)

Proprietary Name:	nordicTumorEx Software
Device Common Name:	PACS
Device:	System, image processing, radiological
Classification Name:	Picture archiving and communication system
Classification Regulation:	892.2050
Class:	II
Panel:	Radiology
Product Code:	LLZ

Predicate device name:	nordic Image Control and Evaluation (nordicICE) Software, K090546 PERFSCAPE V2.0, K111161

Device Description

The nordicTumorEx Software is a post-processing application for dynamic MRI data developed with a view to ease of use and high performance on a standard Windows workstation. The software provides comprehensive functionality for dynamic image analysis and visualization of MRI data, where signal changes over time are analyzed to determine various modality dependent functional parameters. The

software encompass well-established analysis methods and dedicated visualization tools for dynamic contrast enhanced imaging data from MRI where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow (perfusion) and tissue blood volume as well as leakage (due to capillary permeability) of the injected contrast material from the intravascular- to the extracellular space. These parameters and their derived properties together with anatomical/structural MR images are presented to support the diagnostic process.

The application workflow has been optimized to ensure efficiency and high throughput in a clinical environment.

Intended Use

nordicTumorEx is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" PC workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

nordicTumorEx software enables processing and visualization of dynamic MR imaging datasets of the brain, showing properties of changes in contrast over time. It generates various parametric images calculated from the image intensity variations and provides tools to extract and visualize such parametric properties within specified volumes of interest. Structural datasets providing anatomical information can be used to evaluate the extent of a specified sub-volume, such as a tumor. Comparison of imaging studies performed at different study dates may also be performed to support the diagnostic process.

Technological Characteristics and Substantial Equivalence

The nordicTumorEx Software is substantially equivalent to the nordicICE Software (K090546) and PERFSCAPE V2.0 (K111161) in intended use, indications for use, technological characteristics and operational characteristics.

Performance Testing

Prospectively defined verification and validation activities for the nordicTumorEx Software assure that the nordicTumorEx Software meets design and performance specifications as well as user needs when operated according to the operating instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2013

NordicNeuroLab AS
% Mr. Chandana G. Bhandari
Quality Manager
Mollendalsveien 65C
N-5009 Bergen, Hordaland
NORWAY

Re: K123306
Trade/Device Name: nordicTumorEx Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 7, 2013
Received: April 10, 2013

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123306

Device Name: nordicTumorEx Software

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

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