July 19, 2018

Nidek Co., Ltd
% Enrico Bisson
Manager, Regulatory Affairs Department
Nidek Technologies srl
Via dell'Artigianato, 6/A
Albignasego (Padova), 35020 IT

Re: K181345
Trade/Device Name: Image Filing Software NAVIS-EX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: April 30, 2018
Received: May 21, 2018

Dear Enrico Bisson:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181345

Device Name
Image Filing Software NAVIS -EX

Indications for Use *(Describe)*
The Image Filing Software NAVIS -EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.

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.

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510(k) Summary

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Date Summary Prepared: July 17, 2018

Classification:
21 CFR§892.2050

Classification name:
Picture archiving and communications system

Product Code:
NFJ

Trade Name:
Image Filing Software NAVIS-EX

Generic/Common Name:
System, Image Management, Ophthalmic

Predicate and References Devices

	Predicate and Reference Devices	**Holder/Applicant 510(K)**	**510(k) No.**
Predicate device	FORUM, FORUM Archive, FORUM Archive and Viewer	Carl Zeiss Meditec AG	K122938

Reference device	RS-3000 Advance	NIDEK	K132323
Reference device	NON-MYDRIATIC AUTO FUNDUS CAMERA AFC-330 with IMAGE FILING SOFTWARE NAVIS-EX	NIDEK	K113451
Reference device	OPTICAL BIOMETER AL-Scan	NIDEK	K133132
Reference device	Specular Microscope CEM-530	NIDEK	K173980

Indications for use

The Image filing software NAVIS-EX is a software system intended for use to store, manage, process, measure, analyze and display patient data and clinical information from computerized diagnostic instruments through networks. It is intended to work with compatible NIDEK ophthalmic devices.

Product Description

The NAVIS-EX is compatible with the following devices:

- previously cleared NON-MYDRIATIC AUTO FUNDUS CAMERA AFC-330 (K113451);
- previously cleared OPTICAL COHERENCE TOMOGRAPHY RS-3000 Advance (K132323);
- Digital Medical Scope DS-10 (Digital Eye-Fundus Camera DS-10F of the DS-10 was previously cleared under k120982.);
- previously cleared MICROPERIMETER MP-3 by way of the previously cleared MP-Viewer (K152729);
- previously cleared OPTICAL BIOMETER AL-Scan (K133132) by way of the proposed AL-Scan Viewer;

and

- previously cleared SPECULAR MICROSCOPE CEM-530 (K173980) by way of the proposed CEM Viewer

The NAVIS-EX is an application of client-server model. Patient information and examination data are managed in a server database. These data are saved in the database from a device connected with the NAVIS-EX or from software related to the NAVIS-EX. In the client, the examination data can be displayed and analyzed, and the images can be processed. In addition, those results can be printed or be transferred to an external system in the form of a report.

The NAVIS-EX system includes specific optional viewers AL-Scan Viewer, CEM Viewer, and Data Acquisition Service (DAS).

The AL-Scan Viewer is intended to handle the AL-Scan data within NAVIS-EX. The measured value data and waveform can be displayed, the intraocular lens (hereafter referred to as “IOL”) power can be calculated, and the toric lens assist data can be created

The CEM Viewer is intended to view the examination data of the SPECULAR MICROSCOPE CEM-530 or use the data for follow-up within the NAVIS-EX. The examination data is displayed, analyzed, and used for follow-up.
The CEM Viewer can be used to display examination data on the Viewer screen or follow up data on the Follow-Up screen.

The Data Acquisition Service is intended to acquire data from measurement devices such as Optical Biometer AL-Scan and the Specular Microscope CEM-530 and transfers it to the NAVIS-EX. In addition to acquisition of measurement data, the DAS registers patients newly registered with the AL-Scan and CEM-530 to the NAVIS-EX.

Comparison of Technological Characteristics

The NAVIS-EX represents an update of the NAVIS-EX contained in the cleared Nidek devices:

• NIDEK RS-3000 Advance (K132323)
• NIDEK NON-MYDRIATIC AUTO FUNDUS CAMERA AFC-330 with IMAGE FILING SOFTWARE NAVIS-EX (K113451)
• NIDEK MICROPERIMETER MP-3 (K152729)

The comparison table of technological characteristics is here documented.

Filing function

	Subject device	Predicate device	Reference device	Reference device
Device name	Image filing software NAVIS-EX	FORUM, FORUM Archive, FORUM Archive and Viewer	AFC-330 with NAVIS-EX	RS-3000 Advance
Network (Data management)	Yes	Yes	Yes	Yes
Image display	Yes	Yes	Yes	Yes
Search	Yes	Yes	Yes	Yes
Zoom in/out	Yes	Yes	Yes	Yes
Print	Yes	Yes	Yes	Yes

External interface

	Subject device	Predicate device	Reference device	Reference device
Device name	Image filing software NAVIS-EX	FORUM, FORUM Archive, FORUM Archive and Viewer	AFC-330 with NAVIS-EX	RS-3000 Advance
Sending saved image by e-mail	Yes	Unknown	Yes	Yes
Outputting report with saved image and patient information to output designation	Yes	Yes	Yes	Yes
Startup of external application	Yes	Unknown	Yes	Yes
Patient selection from external system	Yes	Yes	Yes	Yes
DICOM	Yes	Yes	No	No

Image acquisition

	Subject device	Predicate device	Reference device	Reference device
Device name	Image filing software NAVIS-EX	FORUM, FORUM Archive, FORUM Archive and Viewer	AFC-330 with NAVIS-EX	RS-3000 Advance
Interfacing with diagnostic devices and acquiring images	Yes	Yes	Yes	Yes
DICOM import	Yes	Yes	No	No
Import function	Yes	Yes	Yes	Yes
Import/export of patient data as well as images	Yes	Yes	Yes	Yes

Image processing

	Subject device	Predicate device	Reference device	Reference device
Device name	Image filing software NAVIS-EX	FORUM, FORUM Archive, FORUM Archive and Viewer	AFC-330 with NAVIS-EX	RS-3000 Advance
Effect (sharpening and blurring)	Yes	Unknown	Yes	No
Color correction (gray scale, color inversion, brightness, contrast, contrast RGB, histogram, channel division, gamma correction, red-free, luminous area detection)	Yes	Yes	Yes	Yes
Rotation/flip	Yes	Unknown	Yes	No
Resize	Yes	Unknown	Yes	No

	Subject device	Predicate device	Reference device	Reference device
Device name	Image filing software NAVIS-EX	FORUM, FORUM Archive, FORUM Archive and Viewer	AFC-330 with NAVIS-EX	RS-3000 Advance
Measurement				
Cup/Disc ratio measurement on fundus images or OCT images	Yes	No	Yes	Yes
Measurement of disc diameter and cup diameter in vertical and horizontal directions on fundus images or OCT images	Yes	Unknown	Yes	Yes
Measurement between 2 points on fundus images or OCT images	Yes	Yes	Yes	Yes
Measurement of area on fundus images or OCT images, measurement of perimeter on fundus images	Yes	No	Yes	No
Measurement of thickness between retinal layer borderline on OCT images	Yes	Unknown	No	Yes
Filter	Yes	Unknown	Yes	No
Simple image processing (RGB, red-free, emboss)	Yes	Unknown	Yes	No
Stereo function	Yes	Unknown	Yes	No
Panorama function	Yes	Unknown	Yes	No
Drawing	Yes	Yes Partially	Yes	No

	Subject device	Predicate device	Reference device	Reference device
Device name	Image filing software NAVIS-EX	FORUM, FORUM Archive, FORUM Archive and Viewer	AFC-330 with NAVIS-EX	RS-3000 Advance
Optical Coherence Tomography (OCT) image display in 3D	Yes	Unknown	No	Yes
Display of position of retinal layer ret/ anterior segment border reference position	Yes	Yes	No	Yes
Editing retinal layer/ anterior segment border	Yes	Unknown	No	Yes
Editing optic disc shape	Yes	Unknown	No	Yes
Recording 3D movie	Yes	Unknown	No	Yes
Followup	Yes	Yes	Yes	Yes

Testing in Support of Substantial Equivalence Determination
Testing according to ISO 14971, AAMI/ANSI/IEC 62304, and IEC 62366-1 demonstrated that the NAVIS-EX performs as intended. The primary predicate device has been tested according to the equivalent standards.

Summary of Safety and Effectiveness
All the necessary safety tests were performed and documented. The results demonstrate that the subject device complies with applicable international standards (ISO 14971, AAMI/ANSI/IEC 62304, and IEC 62366-1) and it is safe as the predicate devices. All the necessary performance tests in support of substantial equivalence determination were conducted. The tests demonstrate that the subject device is effective and performs as well as the predicate devices.

Conclusion:
The proposed and the predicate devices have similar indications for use and technological characteristics. The minor differences between the proposed CEM Viewer and its reference device CEM-530 do not raise any new issues of safety or efficacy because the substantial equivalence of these minor differences are supported by the corresponding, similar functions of the other reference devices. The test results and comparison results show that the proposed device is substantially equivalent to the predicate device in performance.
Based on the intended use, technological characteristics, and performance testing, the proposed NAVIS-EX system has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.