DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 12, 2016

INOVA DIAGNOSTICS, INC.
GABRIELLA LAKOS
DIRECTOR OF ASSAY DEVELOPMENT
9900 OLD GROVE ROAD
SAN DIEGO CA 92131

Re: K153150
Trade/Device Name: NOVA View automated fluorescence microscope with AUTOLoader
Regulation Number: 21 CFR 866.4750
Regulation Name: Automated indirect immunofluorescence microscope and software-assisted system
Regulatory Class: II
Product Code: PIV
Dated October 29, 2015
Received: November 2, 2015

Dear Dr. Lakos:

This letter corrects our substantially equivalent letter of November 24, 2015.

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 Parts 801 and 809); 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**:** Parts 801 and 809**]**), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Kelly Oliner -S

FOR
Leonthena R. Carrington, MS, MBA, MT (ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
NOVA View® Automated Fluorescence Microscope with AUTOLoader

Indications for Use *(Describe)*
NOVA View® Automated Fluorescence Microscope is an automated system consisting of a fluorescence microscope and software that acquires, analyzes, stores and displays digital images of stained indirect immunofluorescent slides. It is intended as an aid in the detection and classification of certain antibodies by indirect immunofluorescence technology. The device can only be used with cleared or approved in vitro diagnostic assays that are indicated for use with the device. A trained operator must confirm results generated with the device.

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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NOVA View® Automated Fluorescence Microscope with AUTOLoader

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Table of Contents

1. Submitter

Inova Diagnostics, Inc

9900 Old Grove Road,

San Diego, CA, 92131

2. Purpose of submission

Special (510) k submission.

The reason for submission is the addition of an optional hardware accessory, AUTOLoader to the NOVA View device.

3. Devices in the submission

NOVA View Automated Fluorescence Microscope with AUTOLoader

4. Primary contact

Gabriella Lakos, Director of Assay development

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5. Secondary contact

Ronda Elliott, VP of Quality Systems and Regulatory Affairs

Inova Diagnostics, Inc.

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Fax: 858-863-0025/1351

email: relliott@inovadx.com

6. Product Information and Classification

6.1 Proprietary and established names

Proprietary name: NOVA View® with AUTOLoader

Common name: Automated Fluorescence Microscope with AUTOLoader

Classification name: Automated indirect immunofluorescence microscope and software-assisted system for clinical use

6.2 Regulatory information

Regulation Description	Automated indirect immunofluorescence microscope and software-assisted system for clinical use
Regulation Medical Specialty	Immunology
Review Panel	Immunology
Product Code	PIV
Regulation Number	866.4750
Device Class	II

7. Intended Use

NOVA View Automated Fluorescence Microscope is an automated system consisting of a fluorescence microscope and software that acquires, analyzes, stores and displays digital images of stained indirect immunofluorescent slides. It is intended as an aid in the detection and classification of certain antibodies by indirect immunofluorescence technology. The device can only be used with cleared or approved in vitro diagnostic assays that are indicated for use with the device. A trained operator must confirm results generated with the device.

8. Indications for Use

NOVA View Automated Fluorescence Microscope is an automated system consisting of a fluorescence microscope and software that acquires, analyzes, stores and displays digital images of stained indirect immunofluorescent slides. It is intended as an aid in the detection and classification of certain antibodies by indirect immunofluorescence technology. The device can only be used with cleared or approved in vitro diagnostic assays that are indicated for use with the device. A trained operator must confirm results generated with the device.

9. Predicate device

NOVA View Automated Fluorescence Microscope

10. Substantial equivalence information

Comparison to the predicate device		
Item	**NOVA View with AUTOLoader**	**Predicate Device: NOVA View**
Intended use	NOVA View is an automated system consisting of a fluorescence microscope and software that acquires, analyses, stores and displays digital images of stained indirect immunofluorescent slides. It is intended as an aid for the trained operator in the detection and classification of certain antibodies with the indirect immunofluorescent technology. NOVA View can only be used with reagents that have been approved for use on the system. Results generated by the NOVA View must be confirmed by trained operator.	Same
Technology	Automated indirect immunofluorescence microscope and software-assisted system for clinical use	Same

11. Regulatory history

De novo submission: DEN140039

12. Type of the Product

Device technology: indirect immunofluorescence and computer controlled digital imaging and image analysis.

13. System Description

13.1. Modes of Operation

The instrument does not process samples. The instrument acquires digital images of representative areas of stained indirect immunofluorescent slides. Slides can be loaded onto the device either manually, or by the AUTOLoader. The use of AUTOLoader is optional.

13.2. Software

The NOVA View instrument is operated by the NOVA View software. Software version is 2.1.4. The AUTOLoader is controlled by the NOVA View software. A module ("AUTOLoader" module) was added to the NOVA View software. This module interfaces between the NOVA View software and the AUTOLoader firmware. In the AUTOLoader tab the user can view the AUTOLoader log files, error messages (if applicable) and can interact with the AUTOLoader. All new functions were tested during software verification, and regression testing has been performed to demonstrate that NOVA View functionality has not changed.

Level of Concern

Based on FDA Guidance, "Guidance for the Contents of Premarket Submissions for Software Contained in Medical Devices" the NOVA View software 2.1.4 has "Moderate" level of concern.

14. Device description

NOVA View is an automated fluorescence microscope that acquires, analyses, stores and displays digital images of stained indirect immunofluorescent slides.

The NOVA View AUTOLoader is an optional hardware accessory that performs the automated transfer of slide carriers to and from NOVA View, thereby providing a continuous load capability without human interaction.

AUTOLoader hardware components consist of a NOVA View alignment base, 3-position stack base, 3 slide carrier stacks (labelled as "Pending", "Completed", "and "Error"), telescoping arm with rotary gripper, and a 2D barcode scanner station. The AUTOLoader can be connected to up to two NOVA View devices.

15. Principle of the Method and Summary of the Procedure

Slides (from NOVA Lite DAPI ANA Kit) are placed in 5-slide carriers. These carriers fit on the microscope stage of NOVA View. Carriers to be scanned on the NOVA View are placed in the Pending stack of the AUTOLoader. One stack can accommodate up to 12 carriers. The AUTOLoader is started by the initiation of the NOVA View software. The AUTOLoader picks up the first slide carrier from the Pending stack, transports it to the barcode station, takes off the slide carrier lid, captures an image of the barcodes on the slides, re-places the slide carrier lid, and then proceeds to place the carrier on the NOVA View stage for scanning. After scanning is complete, the AUTOLoader picks up the slide carrier and transports it to the Completed or Error slide carrier stack (depending on the outcome of the scanning). This procedure is automatically repeated with the rest of the carriers that are in the Pending stack.

16. Analytical performance characteristics

N/A

17. Clinical performance

N/A