June 10, 2021

Digital Diagnostics Inc.
Ashley Miller
Regulatory Affairs Manager
2300 Oakdale Blvd.
Coralville, Iowa 52241

Re: K203629
Trade/Device Name: IDx-DR
Regulation Number: 21 CFR 886.1100
Regulation Name: Retinal Diagnostic Device
Regulatory Class: Class II
Product Code: PIB
Dated: May 11, 2021
Received: May 11, 2021

Dear Ashley Miller:

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,

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*
K203629

Device Name
IDx-DR

Indications for Use *(Describe)*
IDx-DR is indicated for use by healthcare providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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V. 510(k) Summary

I. Submitter

Digital Diagnostics Inc.
2300 Oakdale Blvd.
Coralville, IA 52241
Phone: 319-248-5620

Contact Person: Ashley Miller
Date Prepared: December 4, 2020

II. Device

Name of Device: IDx-DR
Common or Usual Name: Diabetic Retinopathy Detection Device
Classification Name: Retinal diagnostic software device
Regulatory Class: II
Regulation: 21 CFR 886.1100
Product Code: PIB

III. Predicate Device

IDx-DR, Diabetic Retinopathy Detection Device, DEN180001
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Indications for Use

IDx-DR is indicated for use by healthcare providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400.

The Indications for Use statement is identical to the predicate device.

V. Device Description

The IDx-DR device consists of several component parts (see image below). A camera is attached to a computer, where IDx-DR client is installed. Guided by the Client, users acquire two fundus images per eye to be dispatched to IDx-Service. IDx-Service is installed on a server hosted at a secure datacenter. From IDx-Service, images are

transferred to IDx-DR Analysis. No information other than the fundus images is required to perform the analysis. IDx-DR Analysis, which runs on dedicated servers hosted in the same secure datacenter as IDx-Service, processes the fundus images and returns information on the exam quality and the presence or absence of mtmDR to IDx-Service. IDx-Service then transports the results to the IDx-DR Client that displays them to the user.

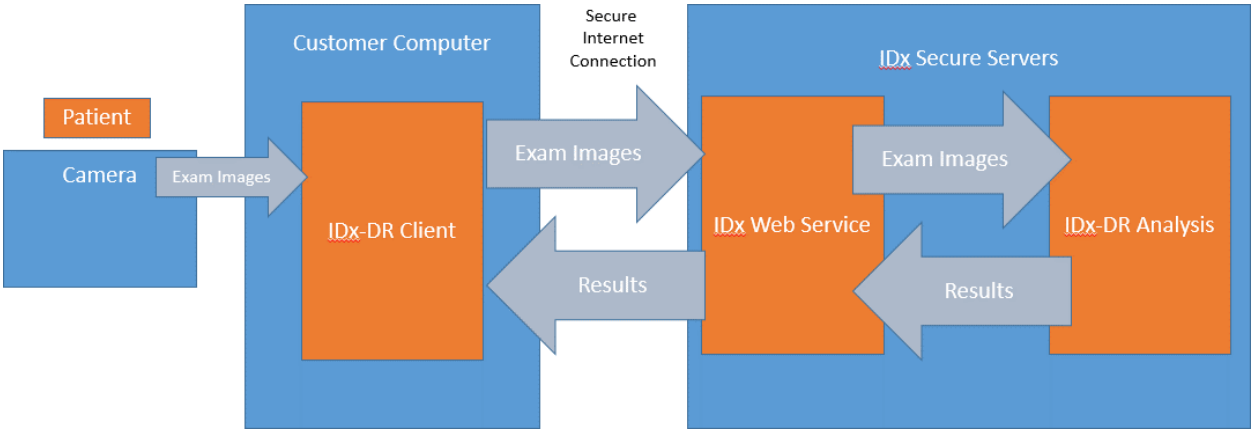

Figure 1: IDx-DR Components

The component parts of IDx-DR illustrated above are summarized as follows:

- IDx-DR Analysis: Software that analyzes the patient's images and determines exam quality and the presence/absence of diabetic retinopathy.
- IDx-DR Client: A software application component running on a computer, usually connected to the fundus camera, at the customer site. Using this software, the customer can transfer images to IDx-DR Analysis via IDx-Service and receive results back.
- IDx-Service: IDx-Service comprises a general exam analysis service delivery software package. IDx-Service contains a webserver front-end that securely handles incoming requests, a database that stores customer information, and a logging system that records information about each transaction through IDx-Service. IDx-Service is also primarily responsible for device cybersecurity.

VI. Comparison of Technological Characteristics with the Predicate Device

IDx-DR, the subject device of this 510(k), has the same intended use and indications for use as the predicate IDx-DR device cleared under DEN180001.

Artificial intelligence software as a medical device is the main technological principle for both the subject and predicate devices. The software as a medical device uses artificial intelligence technology to analyze specific disease features from fundus retinal images for diagnostic screening of diabetic retinopathy. The subject and predicate devices are based on the same general technological elements:

- Fundus camera to obtain retinal images
- IDx-DR Client installed on a computer to guide the user to acquire images using the fundus camera, transfer the images to IDx-DR Analysis via IDx-Service, and receive the results
- IDx-DR Analysis to analyze the patient's images for exam quality and the presence/absence of diabetic retinopathy
- IDx-Service to facilitate secure transfer of exam data from IDx-DR Client to IDx-DR Analysis and the results from IDx-DR Analysis back to IDx-DR Client

The major technological differences that exist between each component of the subject and predicate devices are described below.

IDx-Service

- The subject device allows of the submission of DICOM images
- The subject device provides improved feedback to the client by distinguishing between the states "submission not found" and "submission not ready"
- The subject device tracks image analysis statistics, such as analysis start and end

IDx-DR Client

- The subject device does not require the user to "refresh" the user interface to display new exams
- The subject device incorporates customer configuration options:
    - Submission of DICOM images
    - Output filename structure
    - Highlight most recent exam
    - Masking of exam result on the user interface (the result is unchanged in the final report)
    - Dark mode for viewing based on customer preference
- The subject device incorporates a guided workflow in IDx-DR Client to guide the user through the image acquisition/submission and display step-by-step instructions directly on the user interface
- The subject device incorporates local image retention
- The subject device incorporates a training mode
- The subject device in-exam image quality feedback and allows the user to re-submit images when applicable

IDx-DR Analysis

- The subject device determines image fixations when the number of left and right eye images does not meet protocol requirements

Table 3 provides a comparison between the technical characteristics and indications for use of the subject and predicate devices.

Table 1: Comparison of the Subject and Predicate Device

	Subject Device IDx-DR	**Predicate Device IDx-DR, DEN180001**	**Discussion**
Component Software Versions	IDx-DR Client v3.2.0 IDx-DR Analysis v2.1.1 IDx-Service v1.1.2 See above for the major technological differences between each component of the subject and predicate device.	IDx-DR Client v2.0.1 IDx-DR Analysis v2.0.1 IDx-Service v1.0.0	Substantially Equivalent. The changes described above do not significantly affect the use of the device, clinical functionality, nor performance of the device as supported by software verification and validation testing.
Technological Principle	Artificial intelligence software as a medical device.	Artificial intelligence software as a medical device.	Equivalent
Indications for Use	For use by healthcare providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy.	For use by healthcare providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy.	Equivalent
Indicated Camera	Topcon NW400 fundus camera	Topcon NW400 fundus camera	Equivalent
Inputs	Macula and disc centered color fundus images with 45° field of view, 2 per eye.	Macula and disc centered color fundus images with 45° field of view, 2 per eye.	Equivalent
Outputs	Detection of diabetic retinopathy and referral decision:	Detection of more than mild diabetic retinopathy (mtmDR) and referral decision:	Equivalent

	• mtmDR detected: Refer to an eye care professional • mtmDR not detected: Rescreen in 12 months • Insufficient image quality	• mtmDR detected: Refer to an eye care professional • mtmDR not detected: Rescreen in 12 months • Insufficient image quality	
Architecture	User facing client software transfers images to and receives results from analysis software through a web server.	User facing client software transfers images to and receives results from analysis software through a web server.	Equivalent
Workflow	The graphical user interface includes on-screen prompts to guide the user through the image acquisition workflow one image at a time and submission of the exam.	Labeling (the Quick Reference Guide) guides the user through the image acquisition workflow and submission of the exam.	Substantially Equivalent. The labeling is being incorporated directly into the user interface and instructions are displayed as the user progress through each step for improved interaction with the device. The overall workflow and directions for use do not change.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

A. Summary of Non-clinical Studies

Software

IDx-DR (software version 2) was identified as having a major level of concern as defined in the FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The software documentation includes:

1. Software/Firmware Description
2. Device Hazard Analysis

3. Software Requirement Specifications
4. Architecture Design Chart
5. Software Design Specifications
6. Traceability
7. Software Development Environment Description
8. Revision Level History
9. Unresolved Anomalies
10. Cybersecurity

A comprehensive risk analysis was performed on IDx-DR with identification and detailed description of the hazards, their causes and severity, as well as acceptable methods for control of the identified hazards. A description of acceptable verification and validation activities, at the unit, integration, and system level, including test protocols with pass/fail criteria and a report of the results, was provided. The expected impact of various hardware features on performance was assessed and minimum specifications for acceptable images for analysis were specified.

The cybersecurity considerations of data confidentiality, data integrity, data availability, denial of service attacks, and malware were adequately addressed utilizing platform controls, application controls, and procedure controls, and evidence was provided for the intended performance of the controls. Risks related to failure of various software components and their potential impact on patient reports and operator failures were also adequately addressed in the risk analysis. This software documentation information provided sufficient evidence of safe and effective software performance.

A full characterization of the technical parameters of all of the components of the software, including a description of the algorithms that analyzes the patient's images to determine exam quality and the diagnostic screening of diabetic retinopathy, has been provided. IDx-DR requires one optic disc centered image and one macula centered image from a fundus camera with at least 22 pixels per degree on the retina. So, a 1000 pixel field of view diameter for a 45 degree field of view image.

The IDx-DR artificial intelligence device design has the ability to perform analysis on the specific disease features that are important to a retina specialist for diagnostic screening of diabetic retinopathy. Future algorithm improvements will be made under a consistent medically relevant framework. A protocol was provided to mitigate the risk of algorithm changes leading to changes in the device technical specifications, which would lead to changes in false positive or false negative results. These changes could significantly affect clinical functionality or performance specifications directly associated with the intended use of the device. The protocol specifies the level of change in device specifications that could significantly affect the safety or effectiveness of the device, triggering the requirement for a new 510(k) premarket notification submission before commercial introduction. The protocol incorporates a risk management approach and

other approaches provided in the FDA guidance document *Deciding When to Submit a 510(k) for a Software Change to an Existing Device: Guidance for Industry and FDA Staff* in development, validation, and execution of the device changes.

Usability

Usability validation testing was performed under simulated-use to assess the user interface (IDx-DR Client) of the subject device. The testing was performed in an environment equivalent to the intended use environment of IDx-DR with subjects that had no prior experience using the IDx-DR Client. The critical task for the IDx-DR system is the ability to capture four images of sufficient quality. The purpose of the usability validation test plan was to demonstrate that the intended image capture workflow and training methodology can successfully be used by the intended operators to capture four retinal images. The results of the usability validation study indicated that no existing critical tasks were impacted by the modification and no new critical tasks were introduced, and demonstrated that previously untrained camera operators can capture four retinal images of sufficient quality following the imaging protocol and using the indicated camera system and standardized training and operating materials.

B. Summary of Clinical Studies

The determination of substantial equivalence is not based on an assessment of clinical performance data. The device modifications do not affect clinical performance. Refer to DEN180001 for details about the pivotal clinical trial of the IDx-DR device.

VIII. Conclusions

IDx-DR is substantially equivalent to the predicate IDx-DR device cleared under DEN180001. The subject and predicate devices have the same indications for use, technological characteristics, and performance specifications.