July 16, 2018

Welch Allyn, Inc.
Megan Pellenz
Lead Engineer, Regulatory Affairs
4341 State Street Rd.
Skaneateles Falls, NY 13153

Re: K181016
Trade/Device Name: Welch Allyn RetinaVue™ Network REF 901108 PACS Medical Image System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: April 14, 2018
Received: April 17, 2018

Dear Megan Pellenz:

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,

Alexander Beylin -S
2018.07.16 15:46:15 -04'00'

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)*
K181016

Device Name
Welch Allyn RetinaVue™ Network
REF 901108 PACS Medical Image System

Indications for Use *(Describe)*

The Welch Allyn RetinaVue Network is a web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data, and images from computerized diagnostic instruments. Original and enhanced images can be viewed by trained healthcare professionals.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) –
Welch Allyn RetinaVue™ Network

510(k) SUMMARY
[As required by 21 CFR 807.92]

SUBMITTED BY MANUFACTURER:	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA
ESTABLISHMENT REGISTRATION NUMBER:	1316463
CONTACT PERSON:	Megan Pellenz Lead Engineer, Regulatory Affairs Phone: 1-315-685-4696 Fax: 1-315-685-2532
DATE PREPARED:	Updated July 3, 2018
DEVICE TRADE NAME:	Welch Allyn RetinaVue™ Network REF 901108 PACS Medical Image System
COMMON NAME:	System, Image Management, Ophthalmic
REGULATION NUMBER:	21 CFR 892.2050
DEVICE CLASS:	II
PRODUCT CODE:	NFJ
PREDICATE DEVICE:	Zeiss FORUM® FORUM Archive, FORUM Viewer (K122938)

DESCRIPTION OF THE DEVICE:
The RetinaVue Network software enables providers to transfer eye images.

1. Transfer images via the Client or Customer portal to the database for storage and/or to the Over-read (Physician) Portal for interpretation.
2. Allow for the enhancement and interpretation of images and report generation at the Over-read (Physician) Portal.

3. Transfer reports from the Over-read (Physician) Portal to the Customer Portal for download.

INTENDED USE/INDICATIONS FOR USE:
The Welch Allyn RetinaVue Network is a web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data, and images from computerized diagnostic instruments. Original and enhanced images can be viewed by trained healthcare professionals.
Prescription only or "For Use by or on the order of a licensed medical professional".

CONTRAINDICATIONS:
There are no known contraindications.

TECHNOLOGICAL CHARACTERISTICS:
RetinaVue Network (RVN) is a web-based software application that works on standard network infrastructure provided by the user. RetinaVue Network consists of these main software items: RVN Client Application, RVN Web Service, RVN Database, Overread Physician Portal and Customer Portal.

RVN Client Application
The RVN Client Application provides the user interface for the Clinician. Its main functions are to obtain and present patient information along with an Eye Image from an Ophthalmic Camera to be submitted to the Overread Physician Portal.

RVN Web Service
The RVN Web Service provides the client application programming interface (API) for the RVN Client application to allow it to maintain its configuration and support taking and submitting images to the Overread Physician Portal.

RVN Database
The RVN Database is a database used to store data common to other RVN software items such as patient demographics, user account management, RVN Client application install inventory and configuration, wireless device inventory and configuration, customer account and clinic information, exam reports and billing information.

Overread Physician Portal
The Overread Physician Portal is an ASP.NET web application that allows physicians to over-read the exam images and to produce a diagnostic report. Functions the overread physician portal supports: ability to overread exams submitted from customers, ability to view enhanced versions of the ophthalmic images submitted to RVN, creation of PDF files of the over-read diagnostic report and ability to view statistical reports about the current user's use of the over-read portal.

Enhanced versions of ophthalmic images are the result of CLAHE – Contrast Limited Adaptive Histogram Equalization algorithms. Enhancement filters for Brightness/Contrast, Sharpen, Saturate and Chromium are available.

Customer Portal

The Customer Portal is an ASP.NET web application that allows a customer to centrally maintain company and clinic data, user accounts, contacts, referring physicians, patient demographics, exam reports and wireless camera management.

COMPARISON TO THE PREDICATE DEVICE:

It is of the opinion of Welch Allyn, Inc. that RetinaVue Network is substantially equivalent to the predicate device, Zeiss FORUM® FORUM Archive, FORUM Viewer (K122938) as they share similar fundamental technical characteristics, intended use including indications for use, target population and use environment.

Characteristic	*Predicate Device*	*Subject Device*	*Differences*
Device Name	FORUM	RetinaVue Network	N/A
Manufacturer	Carl Zeiss Meditec AG	Welch Allyn, Inc.	N/A
510(k) Number	K122938	K181016	N/A
Product Code	NFJ	NFJ	Same
Device Class CFR Section Common Name	Class II 21 CFR 892.2050 System, image management, ophthalmic	Class II 21 CFR 892.2050 System, image management, ophthalmic	Same
Indications for Use	FORUM is a software system intended for use in storage, management, processing, and display of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications. FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.	The Welch Allyn RetinaVue Network is a web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data, and images from computerized diagnostic instruments. Original and enhanced images can be viewed by trained healthcare professionals.	Similar – We have simplified the statement somewhat
Basic Description	FORUM is software for managing, archiving, and viewing e.g. patient data, images, videos, and reports provided by computer-controlled diagnostic devices or other documentation systems.	The Welch Allyn RetinaVue Network is a system for the transmission of eye images, associated patient data, and diagnostic reports from one location to another via the internet.	Equivalent – both software systems are for transmission, storage and viewing of eye images and associated data

Characteristic	*Predicate Device*	*Subject Device*	*Differences*
Target Population	Images / system is not patient population specific.	Images / system is not patient population specific	Same
Where Used	Throughout the patient care process	Throughout the patient care process	Same
Software Design Features			
RVN Client Application			
Entering and editing patient and exam information	Yes	Yes	Same
Managing application behavior and camera specific settings	Will accept all images.	For additional security, our system will only communicate with cameras known to the system. This feature is to register the camera in the system.	Similar – Additional communications security in our system
Entering and editing contact information	No	Yes	Similar – We allow patient contact information to be included in our patient database
RVN Web Service			
Ability to query and report the status for submitted exams	Yes	Yes	Same
Maintain patient demographic information	Yes	Yes	Same
Maintain Contact and User account information	No	Yes	Similar – We allow patient contact information to be included in our patient database
Maintain last known set of configurations	unknown	Yes	Minor – unable to determine Zeiss's recovery capability from the documentation available to us from Zeiss
Obtain encryption keys to encrypt data with	unknown	Yes	Minor – unable to determine Zeiss's from the documentation available to us from Zeiss
RVN Database			
Patient Demographics	Yes	Yes	Same
User Account Management (user roles)	Yes	Yes	Same

RVN Client application install inventory and configuration	Yes	Yes	Same
Wireless device inventory and configuration	No	Yes	Minor – We allow wireless communications
Customer Account and Clinic information	No: Customer Account Yes: Clinic information	Yes – both	Minor – We store additional patient account/contact data
Exam Reports	Yes	Yes	Same
Billing Information	No	Yes	Minor – We store additional patient account/contact data
Overread Physician Portal			
Ability to overread exams submitted from customers	Yes	Yes	Same
Ability to view enhanced versions of the ophthalmic images	Yes	Yes	Same
Creation of PDF files of the over-read diagnostic report	Yes	Yes	Same
Ability to view statistical reports about the current user's use of the over-read portal	No	Yes	Minor – We provide statistical report to allow clinic to monitor their activities (not directed at patientcare)
Customer Portal			
Company and clinic data	Yes	Yes	Same
User accounts	Yes	Yes	Same
Contacts	Yes	Yes	Same
Referring Physicians	Yes	Yes	Same
Patient Demographics	Yes	Yes	Same
Exam Screening reports	Yes	Yes	Same
Wireless camera management	No	Yes	Minor – We allow wireless communications
Technology			
EMR Interface	Yes	Yes	Same
HL7	Yes	Yes	Same
Image Enhancement and Measurement			
Brightness/Contrast	Yes	Yes	Same
Sharpen	No	Yes	Minor – Filter only applied during review. Native image maintained

Saturate	No	Yes	Minor – Filter only applied during review. Native image maintained
Chromium (greyscale)	No	Yes	Minor – Filter only applied during review. Native image maintained
Pan/Zoom	Yes	Yes	Same
Image Measurements	Yes	No	Minor – Predicate offers option of performing measurements of calibrated ophthalmic images
Image formats			
PDF	Yes	Reports only	Minor – We supply report images in .pdf
JPEG	Yes	Yes	Same
TIFF	Yes	Reports only	Minor – We supply report images in .tif
DICOM	Yes	Yes	Same

PERFORMANCE DATA:
RetinaVue Network is a software-only device and was designed and tested within the framework as defined by ISO 14971:2007 *Medical devices - application of risk management to medical devices*, FDA Guidance dated October 2, 2014 *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, FDA Guidance dated January 11, 2002 *General Principles of Software Validation* and IEC 62304:2006 *Medical device software - software life cycle processes*. Usability engineering/human factors testing and was performed in accordance with FDA Guidance dated February 3, 2016 *Applying Human Factors and Usability Engineering to Medical Devices* and IEC 62366-1:2015-02 incl. Corr. (2016) *Application of Usability Engineering to Medical Devices*.

RetinaVue Network is DICOM compliant as stipulated in its DICOM Conformance Statement.

Performance testing confirmed that RetinaVue Network performs as intended, supports the indications for use statement, demonstrates that the device is substantially equivalent to the predicate, and does not raise new questions regarding safety and effectiveness.

CLINICAL PERFORMANCE DATA:
None required nor submitted.

CONCLUSIONS:
The Welch Allyn RetinaVue Network is substantially equivalent in operation and performance to the Carl Zeiss Meditec AG FORUM (K122938). The introduction of the Welch Allyn RetinaVue Network to the medical market raises no new questions of safety and effective and we therefore request clearance to proceed to market.