December 24, 2020

VisionQuest BioMedical, Inc.
℅ Ryan Bouchard
VP Medical Devices
Ora
300 Brickstone Square
Andover, Massachusetts 01810

Re: K200422
Trade/Device Name: Image Quality Analyzer (IQA)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: November 19, 2020
Received: November 20, 2020

Dear Mr. Bouchard:

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,

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200422

Device Name
Image Quality Analyzer (IQA)

Indications for Use *(Describe)*
IQA is a software system intended for use in importing, displaying, analyzing and managing images acquired with digital fundus cameras.

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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VisionQuest Biomedical, Inc.

510(k) Premarket Notification for the IQA Image Quality Analyzer

510(k) Summary

This summary of the 510(k) premarket notification for the IQA Image Quality Analyzer is being submitted in accordance with the requirements of 21 CFR 807.92.

a. Owner Company name, address

VisionQuest Biomedical, Inc
2501 Yale Blvd, SE, #301
Albuquerque, NM 87106
GZamora@visionquest-bio.com

b. Contact/Application Correspondent

Ryan Bouchard
Ora, Inc.
300 Brickstone Square
Andover, MA 01810
Telephone: (978) 332-9574
Facsimile: (978) 689-0020
E-mail: rbouchard@oraclinical.com

c. Date Prepared

23 December 2020

d. Name of Device

Trade Name:	Image Quality Analyzer (IQA)
Common Names:	Picture Archiving and Communication System
Classification Name:	System, Image Management, Ophthalmic
Product Code:	NFJ
Classification Regulation:	21 CFR 892.2050

e. Predicate Device

The Image Quality Analyzer (IQA) is substantially equivalent with the Welch Allyn RetinaVue Network cleared in K181016

f. Device Description

The VisionQuest Biomedical Image Quality Analyzer (IQA) is an ophthalmic software system intended to import, display, analyze, and manage retinal images from Canon CR2, Canon CR2-AF, Volk Pictor Plus and Zeiss VisuScout retinal cameras.

IQA is a software application that is used to assess the quality of retinal images acquired with supported non-mydriatic retinal cameras. All images acquired by the retinal camera passed to the IQA undergo an image quality calculation process and the results are presented to the user in five seconds or less.

Image quality is assessed based on the presence and extent of three imaging artifacts: crescents, shadows, and blurriness. An image quality output of "Adequate" or "Inadequate" is calculated automatically by IQA based on a set of pre-determined thresholds on the three imaging artifacts. The image quality output can be used by the IQA user to determine whether a retinal image should be re-acquired or not. IQA does not modify the retinal images. The images processed by the IQA can be used for further processing, manual or automatic grading, or made available to an image management system such as a PACS.

Adequate images are automatically moved by the IQA to a user-defined "Save" folder in the computer. The user can manually instruct the IQA to move inadequate images to the same Save folder, thus overriding the IQA, or to a user-defined "Discard" folder to segregate the inadequate quality images from adequate quality images in the "Save" folder. Regardless of whether an image is adequate or inadequate, IQA does not modify the image and only moves the image from the input folder to either the Save or Discard folder.

The retinal images moved to the Save folder can be made available to other steps in the clinical flow such as a PACS, manual or automatic grading, or archiving.

IQA generates an activity log that captures the images processed, the timestamp of the processing, the user's initials, a session number, the output result, the actions of the user, and the values of the image quality calculations with respect to the three imaging artifacts. This log is a comma-separated-value file (csv) that can be retrieved from the computer running the IQA and read in any of a variety of analytical software tools such as MS Excel or R.

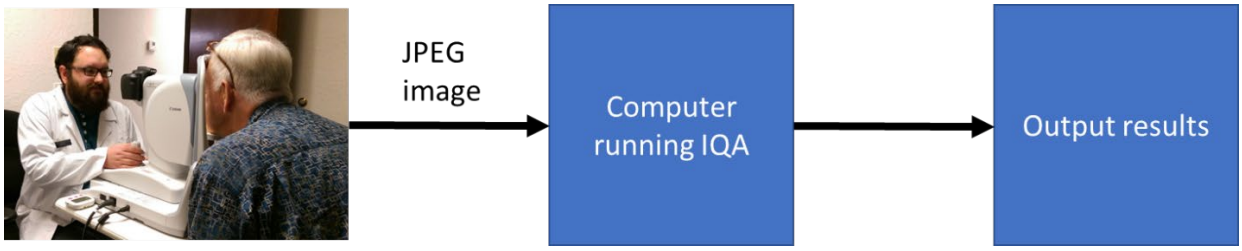

Figure 1: IQA Overview

IQA works as a part of a clinical workflow to help minimize the acquisition of retinal images of inadequate quality and improve the reading efficiency of human graders or automatic grading software. As such, IQA acts as a middle-ware between a retinal camera and an image management system, such as a PACS. IQA helps a user, normally a retinal photographer, capture images of adequate quality that can then be used for further processing. Similarly, IQA helps the user segregate images of inadequate quality so they are not used for further processing. Thus, the

output results of IQA are limited to labeling a retinal image as Adequate or Inadequate as depicted in **Figure 2.** IQA receives as inputs retinal images in JPEG format which have been captured by a trained photographer using a supported retinal camera. The computer that runs IQA then produces an output for each image.

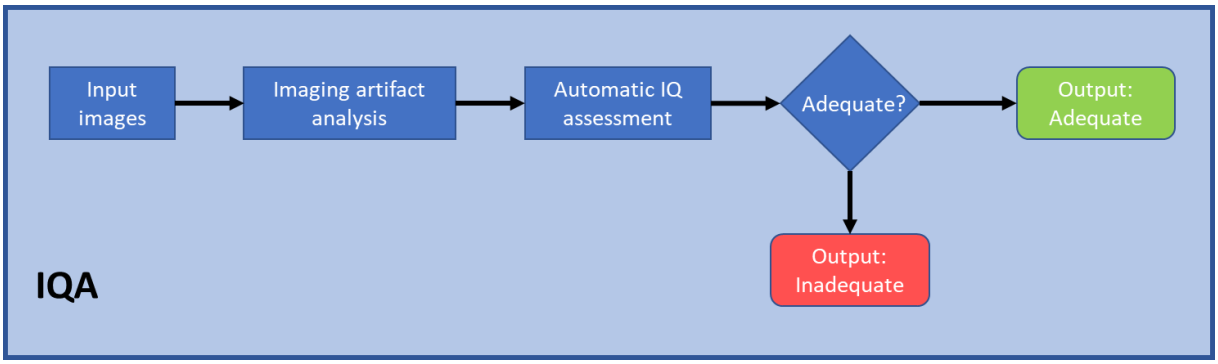

Figure 2: IQA Workflow

Figure 2 shows the workflow of the IQA. The images captured with the retinal camera are copied to the IQA "Fetch" folder in JPEG format. IQA then automatically analyzes the quality of the images. When the result of the analysis is that an image is adequate, IQA automatically moves the image to the user-defined Save directory and waits for the user to take the next image, start a new session or stop IQA image processing. When the result of the analysis is that the image is inadequate, IQA displays the results to the user and waits for the user's decision to move the image to either the Save or Discard folder.

IQA's automatic image quality algorithms determine if the images contain any of three different artifacts (Imaging artifact analysis block in Figure 2) namely bright artifacts (crescents), shadows, or blurriness that could degrade the ability of a human or a computer-based algorithm to determine the presence of retinal disease.

If an image does not have sufficient image quality, IQA returns an output of "Inadequate". When this is the case, IQA presents the operator with two options, either to Save or Discard the inadequate image. It is recommended that the operator try to capture another image from the patient to ensure appropriate quality. This is done by discarding the inadequate image and taking another one. Images moved to the Discard folder are segregated from further processing and remain in the Discard folder for retrieval if desired.

When an image has adequate image quality, IQA will automatically move it to the user-defined Save directory and display a thumbnail in the IQA user interface. Then the operator can continue the imaging process. Images moved to the Save folder are available for further processing according to the site's clinical flow and standard operating procedures.

IQA can process as many images as are acquired regardless of the field of view or number of previously acquired images. It is up to the operator to determine whether sufficient images of adequate quality have been acquired from a patient.

g. Indications for Use

IQA is a software system intended for use in importing, displaying, analyzing and managing images acquired with digital fundus cameras.

h. Statement of Substantial Equivalence

As shown in Table 1, the VisionQuest Biomedical IQA is substantially equivalent to the Welch Allyn RetinaVue Network cleared in K181016. As explained in more detail below, the IQA has the same intended use and similar indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device**.**

Table 1: IQA Substantial Equivalence Table

	Proposed Device	Predicate Device
Model	VisionQuest Biomedical IQA	Welch Allyn RetinaVue Network REF 901108 PACS Medical Image System
Description		
510(k) Submitter [Number]	VisionQuest Biomedical [K200422]	Welch Allyn, Inc [K181016]
Product Code	NFJ	NFJ
Indications for Use	The VisionQuest Biomedical Image Quality Analyzer (IQA) is a software system intended for use in importing, displaying, analyzing and managing retinal images acquired with digital fundus cameras.	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.
Device Design		
Type of Retinal Camera used in conjunction with	Non-mydriatic	Non-mydriatic Mydriatic
Patient Management	Not Supported	Supported
Site Management	Not Supported	Supported
User Management	Not Supported	Supported
View Image	Supported	Supported
Automated image quality assessment	Supported	Supported
Software requirements	Microsoft Windows 10	Windows 7 with SP1 32-bit and 64-bit, Windows 8.1 64-bit, or Windows 10 with latest SP RetinaVue Network Prerequisite software requirements: • Microsoft Visual C++ 2013 Runtime Libraries (x86) • Microsoft .NET Framework 4.5 • Web browser Internet Explorer (version 11 or greater), Chrome for Windows (latest version) • Certificates Go Daddy Root certificate Authority installed on the computer
Hardware Requirements	• ≥8GB RAM • ≥250 GB solid state drive • Dual core microprocessor with a clock speed ≥ 2.3 GHz • Other computer features that help improve the IQA user experience include:	RAM ≥ 2 GB CPU ≥1 GHz • Hard disc 150 MB free HHD space, 16 GB free HHD space or greater recommended • Monitor resolution 1280 x 720 recommended

	Proposed Device	Predicate Device
	○ At least 20GB of free hard drive space ○ Color video display with a resolution of at least 800 x 600 pixels ○ Keyboard ○ Mouse or trackpad	• Ethernet Port RJ-45 • Ports 2 USB, 2.0 port or greater • High-speed Internet connection • Broad-band Internet connection (minimum download speed 1.5 Mbps) • Firewall Ability to connect to www.retinavue.net on ports 80 and 443 with *RetinaVue Network.exe*
Cameras that are compatible	Canon CR2, Canon CR2-AF, Volk Pictor Plus and Zeiss VisuScout retinal cameras.	Not device specific
File Location	Local Application	Network
Software Location	Local drive installation	Local drive installation
Camera choice menu	Not supported	Supported
Clinic Management	Not supported	Supported
User Management	Not supported	Supported
Patient Management	Not supported	Supported
Physician Management	Not supported	Supported
Diagnostic Data	Not supported	Supported
Image acquired from camera	Supported	Supported
Image reviewed from file	Supported (fetch Folder)	Supported
-Save folder	Supported	Supported
-Discard folder	Supported	Supported
Visual quality indicator	Supported	Supported
Poor quality images forces retake	No	Yes
All images saved?	Yes	No
Fair or good images reviewed by Reader	Supported	Supported
Customer portal	Not supported	Supported
Choose input camera	Not supported	Supported
Enforce image quality function	Yes	Yes
Quality Evaluation Basis	Artifact evaluation	Quality Assurance score of $\geq$20
On-line installation	Supported	Supported
Audit trail	Log of image review sessions	Audit trail
Anterior Segment Images	Supported	Not supported

Substantial Equivalence Discussion for the IQA per the 510(k) Decision-Making Flowchart

1. Is the predicate device legally marketed?

Yes, the predicate device is the Welch Allyn RetinaVue Network REF 901108 PACS Medical Image System cleared in K181016.

2. Do the devices has the same intended use?

The devices have the same intended use with regards to image quality assessment. The indications for use are similar in that both devices import images from ophthalmic devices for analysis, display and management. The IQA is an ophthalmic image assessment and management system which has an intended use of image quality assessment and the management of the images to achieve this intended use. The predicate device also contains an image quality assessment component. The Welch Allyn RetinaVue Network REF 901108 PACS Medical Image System cleared in K181016 is an ophthalmic image management system that also includes site, practitioner and patient management functions and includes an image quality assessment function in the RVN Client Application that provides similar output as the IQA.

3. Do the devices have the same technological characteristics?

The IQA and the predicate device are both ophthalmic image management systems that collect, store, and manage digital images of the eye. The IQA has similar functions as the RVN Client Application in the predicate.

The predicate device is designed to do more than just evaluate image quality. The predicate includes RVN Web Service, RVN Database, an Overread Physician Portal and a Customer portal in addition to the RVN Client Application. The predicate is a web-based software system application used for storing, managing, and displaying patient data, diagnostic data, and images from computerized diagnostic instruments. It contains a number of management functions designed for network data management. These functions are not applicable in comparison to the IQA. However, the predicate system has a function within the RVN Client Application in which images are accessed for quality assessment and stored after assessment for viewing by a qualified reader. The means by which the system makes the quality assessment is to note that the images are graded based on a quality assurance score. The system requires images to be retaken if the image result is "Poor". If the operator is unable to get a good image after three attempts the system will allow a "Poor" image to be passed through to be read.

The IQA is a local system for storing, managing, and displaying ophthalmic images to provide a quality assessment during the image management process. Images are placed in a "Fetch" folder, accessed by the IQA system for quality assessment and moved and stored after assessment for viewing by a qualified reader. The method by which the system makes the quality assessment is through the evaluation of three imaging artifacts: crescents, shadows, and blurriness. All images graded as "inadequate" are stored in a folder to be read if desired.

Both the IQA and the predicate device are designed to provide high quality images to a qualified reader and reduce the number of poor or inadequate images that must be read.

Therefore, the differences between the predicate RVN Client Application and the IQA application with regard to the processes of image quality assessment do not raise new questions of safety or effectiveness. The IQA is as safe and effective as its predicate device, and thus, may be considered substantially equivalent.

h. Performance Testing

Voluntary standards apply under Section 514 of the FDC Act for Ophthalmic Image Management Systems. Special controls include voluntary standards and standards for Digital

Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern. Of these only JPEG is applicable to the use of this device as neither DICOM nor SMPTE images are used by the device.

The IQA complies with the following voluntary standards:

Standard Number	Standard Title
21 CFR Part 820.30	Quality System Regulation
ISO 13485:2016	Quality Systems – Medical Devices
ISO 14971:2012	Medical devices — Application of risk management to medical devices
IEC 62304:2006 / AMD1:2015	Medical device software – Software life cycle processes
ANSI/AAMI/IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices

Bench performance testing was performed and the results are summarized below.

1. IQA Verification Testing

   The conclusion for the IQA software verification test report is that the released IQA software, version 2.0.934, successfully meets the passing criteria of the IQA verification protocol and IQA verification protocol addendum, thus demonstrating that the IQA software satisfies the IQA software requirements specification, version 3.

2. IQA SW Verification Protocol Addendum: 1-Functional Requirements

   The testing demonstrated that the features under test satisfied the functional requirements.

3. IQA SW Verification Protocol: 1-Functional Requirements

   The testing demonstrated that the features under test satisfied the functional requirements and any deviations were noted.

4. IQA SW Image Classification Results

   In order to test the IQA device, VisionQuest Biomedical Inc. fed the IQA platform with retinal images from the supported cameras per the summary matrix below. These images were known to have “adequate” or “inadequate” quality as rated by an expert with specific artifacts. A total number of 182 “adequate” images were analyzed and the software successfully identified 181 of them as “adequate”. The success rate is 99.45%, better than the prespecified acceptance criterion of 90%. The image that was not identified as adequate was identified as an anterior segment image, in which case, the IQA requested the input from the user. A total number of 166 “inadequate” images were analyzed and the software identified all of them as “inadequate”. The 100% success rate is better than the 90% acceptance criterion. The below matrix details the results by camera type for the “adequate” and “inadequate” images. The “inadequate” results are also subcategorized by the type of artifact on the image that was present which resulted in the “inadequate” result.

Number of images per camera

Camera	No. of Images
Canon CR 2	109
Canon CR 2 AF	113
Pictor Plus/Visuscout	126
Total number of images	**348**

Number of adequate images per camera

Camera	No. of Images
Canon CR 2	55
Canon CR 2 AF	60
Pictor Plus/Visuscout	67
Total number of adequate images	**182**

Number of inadequate images per camera

Camera	No. of Images
Canon CR 2	54
Canon CR 2 AF	53
Pictor Plus/Visuscout	59
Total number of inadequate images	**166**

Number and types of artifacts per camera in the inadequate image set

Camera	Crescents	Blur	Shadows	Crescents and Blur	Crescents and Shadows	Blur and Shadows	All Three Artifacts	Total
Canon CR 2	5	26	6	10	0	7	0	54
Canon CR 2 AF	0	21	10	19	0	3	0	53
Pictor Plus/Visuscout	5	32	6	8	0	8	0	59
Total number of inadequate images	**10**	**79**	**22**	**37**	**0**	**18**	**0**	**166**

No clinical performance testing was performed for this device.

i. Conclusion

The IQA has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate. A substantial equivalence chart comparing the similarities and differences between the subject device and its predicate device demonstrates substantial equivalence.