Paige.AI, Inc
Mufaddal Jafferji
Director of Quality and Compliance
11 Times Sq, Floor 37
New York, NY 10036

January 9, 2025

Re: K241273
Trade/Device Name: FullFocus
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: May 6, 2024
Received: May 6, 2024

Dear Mufaddal Jafferji:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shyam Kalavar -S

Shyam Kalavar
Deputy Branch Chief
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241273

Device Name
FullFocus

Indications for Use *(Describe)*
For In Vitro Diagnostic Use

FullFocus is a software intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret and manage digital images of pathology slides for primary diagnosis. FullFocus is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. FullFocus is intended to be used with the interoperable components specified in the below Table.

Table: Interoperable components of FullFocus

Scanner Hardware	**Scanner Output file format**	**Interoperable Displays**
Leica Aperio GT 450 DX scanner	DICOM, SVS	Dell UP3017 Dell U3023E Dell U3223QE JVC-Kenwood JD-C240BN01A
Hamamatsu NanoZoomer S360MD Slide Scanner	NDPI	

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

FullFocus

Date Prepared: January 8, 2025

Submitter

Paige.AI, Inc.
11 Times Square, 37th Floor
New York, NY 10036

Contact Person

Mufaddal Jafferji
Director of Quality and Compliance
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Device

Proprietary Name of the Device:	FullFocus
Version:	2.29
Classification Name:	Whole Slide Imaging System
Regulation Number:	21 CFR 864.3700
Product Codes:	QKQ
Device Class:	Class II
Review Panel:	88 – Pathology
Common Name:	FullFocus
510(k) Number:	K241273

Predicate Devices

Trade name:

1. Aperio GT450X (K232202)
   Manufacturer: Leica Biosystems Imaging, Inc.
2. NanoZoomer S360MD Slide scanner system (K213883)
   Manufacturer: Hamamatsu Photonics K.K.

Device Class: Class II
CFR section: 864.3700
Product code: PSY
Classification name: Whole Slide Imaging System

Device Description

FullFocus, version 2.29, is a web-based software-only device that facilitates the viewing and navigating of digitized pathology images of slides prepared from FFPE-tissue specimens acquired from FDA cleared digital pathology scanners on FDA cleared displays. FullFocus renders these digitized pathology images for review, management and navigation for pathology primary diagnosis.

Image acquisition is performed using the intended scanner (s), with the operator conducting quality control on the digital WSI images according to the scanner's instructions for use and lab specifications to determine if re-scans are needed. Please see the Intended Use section and below tables for specifics on scanners and respective displays for clinical use.

Once a whole slide image is acquired using the intended scanner and becomes available in the scanner's database file system, a separate medical image communications software (not part of the device), automatically uploads the image and corresponding metadata to persistent cloud storage. Integrity checks are performed during the upload to ensure data accuracy.

The subject device enables the reading pathologist to open a patient case, view the images, and perform actions such as zooming, panning, measuring distances and areas, and annotating images as needed. After reviewing all images for a case, the pathologist will render a diagnosis.

FullFocus operates with and is validated for use with the FDA cleared components specified in the tables below:

Table 1: Interoperable Components Intended for Use with FullFocus

Scanner Hardware	Scanner Output file format	Interoperable Displays
Leica Aperio GT 450 DX scanner	DICOM, SVS	Dell UP3017 Dell U3023E Dell U3223QE JVC-Kenwood JD-C240BN01A
Hamamatsu NanoZoomer S360MD Slide Scanner	NDPI	

FullFocus version 2.29 was not validated for the use with images generated with Philips Ultra Fast Scanner.

Table 2: Computer Environment/System Requirements for during the use of FullFocus

Environment	Component	Minimum Requirements
Hardware	Processor	1 CPU, 2 cores, 1.6GHz
	Memory	4 GB RAM
	Network	Bandwidth of 10Mbps
Software	Operating System	• Windows • macOS
	Browser	• Google Chrome (129.0.6668.90 or higher) • Microsoft Edge (129.0.2792.79 or higher)

Intended Use/Indications for Use

FullFocus is a software intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret and manage digital images of pathology slides for primary diagnosis. FullFocus is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. FullFocus is intended to be used with the interoperable components specified in the below Table.

Table: Interoperable components of FullFocus

Scanner Hardware	**Scanner Output file format**	**Interoperable Displays**
Leica Aperio GT 450 DX scanner	DICOM, SVS	Dell UP3017 Dell U3023E Dell U3223QE JVC-Kenwood JD-C240BN01A
Hamamatsu NanoZoomer S360MD Slide Scanner	NDPI	

Summary of Technological Characteristics

Comparison with Predicate (Aperio GT 450X):

<table>
<tr><th>Item</th><th>Subject Device (FullFocus)</th><th>Predicate Device (K232202)</th></tr>
<tr><td>Device Trade Name</td><td>FullFocus</td><td>Aperio GT 450 DX</td></tr>
<tr><td>Intended Use /Indications for Use</td><td>FullFocus is a software intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret and manage digital images of pathology slides for primary diagnosis. FullFocus is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. FullFocus is intended to be used with the interoperable components specified in the below Table.

Table: Interoperable components of FullFocus
<table>
<tr><th>Scanner Hardware</th><th>Scanner Output file format</th><th>Interoperable Displays</th></tr>
<tr><td>Leica Aperio GT 450 DX scanner</td><td>DICOM, SVS</td><td rowspan="2">Dell UP3017
Dell U3023E
Dell U3223QE
JVC-Kenwood JD-C240BN01A</td></tr>
<tr><td>Hamamatsu NanoZoomer S360MD Slide Scanner</td><td>NDPI</td></tr>
</table></td><td>The Aperio GT 450 DX is an automated digital slide creation and viewing system. The Aperio GT 450 DX is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. The Aperio GT 450 DX is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy.

Aperio GT 450 DX is comprised of the Aperio GT450 DX scanner, which generates images in the Digital Imaging and Communications in Medicine (DICOM) and in the ScanScope Virtual Slide (SVS) file formats, the Aperio WebViewer DX viewer, and the displays. The Aperio GT 450 DX is intended to be used with the interoperable components specified in Table 1.
Table 1: Interoperable components of Aperio GT 450 DX
<table>
<tr><td>Scanner Hardware</td><td>Scanner Output file format</td><td>Interoperable Viewing Software</td><td>Interoperable Displays</td></tr>
<tr><td>Aperio GT 450 DX scanner</td><td>SVS</td><td>Aperio WebViewer DX</td><td>Barco MDPC-8127
Dell UP3017
Dell U3023E
Dell U3223QE</td></tr>
<tr><td>Aperio GT 450 DX scanner</td><td>SVS</td><td>Sectra Digital Pathology Module (3.3)</td><td>Dell U3223QE</td></tr>
<tr><td>Aperio GT 450 DX scanner</td><td>DICOM</td><td>Sectra Digital Pathology Module (3.3)</td><td>Dell U3223QE</td></tr>
</table></td></tr>
<tr><td>Specimen Type</td><td>Digitized surgical pathology slides prepared from FFPE tissue</td><td>Same</td></tr>
<tr><td>Image file format</td><td>• SVS & DICOM - Aperio GT450 DX
• NDPI – Hamamatsu NanoZoomer S360MD Slide scanner</td><td>SVS & DICOM</td></tr>
<tr><td>Image Manipulation Functions</td><td>Panning, zooming, annotations, and measurements</td><td>Same</td></tr>
<tr><td>Type of Software Application</td><td>Internet browser-based application</td><td>Same</td></tr>
<tr><td>Device Components</td><td>FullFocus</td><td>Scanner, Webviewer DX, Display</td></tr>
<tr><td>End User’s Interface</td><td>FullFocus</td><td>WebViewer DX, Sectra Digital Pathology Module (3.3)</td></tr>
<tr><td>Principle of Operation</td><td>After WSI images are successfully acquired by using Aperio GT 450 DX scanner or Hamamatsu NanoZoomer S360MD Slide scanner, the WSI images are stored in the cloud. During review, the</td><td>The Aperio GT 450 DX is a WSI system. The technician places the slides into the Aperio GT 450 DX scanner. The Aperio GT 450 DX scanner automatically loads the slides, takes the micro images, finds the tissues, and scans the slides. The scanner also automatically</td></tr>
</table>

	pathologist opens WSI images from storage, perform further QC and reads WSI images of the slides render a diagnosis.	performs quality control (QC) and notifies the user of any image quality issue during the image acquisition. The image data is sent to end-user-provided image storage attached to the local network. During the review, the pathologist opens WSI images acquired with the WSI scanner from the image storage, performs further QC, and reads WSI images of the slides to make a diagnosis.
Image Storage	Images are stored in the cloud	Images are stored in the end-user provided image storage attached to the local network

Comparison with Predicate (Hamamatsu NanoZoomer S360MD slide scanner system)

<table>
<tr><th>Item</th><th>Subject Device (FullFocus)</th><th>Predicate Device (K213883)</th></tr>
<tr><td>Device Trade Name</td><td>FullFocus</td><td>NanoZoomer S360MD Slide scanner system</td></tr>
<tr><td>Intended Use /Indications for Use</td><td>FullFocus is a software intended for viewing and management of digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. It is an aid to the pathologist to review, interpret and manage digital images of pathology slides for primary diagnosis. FullFocus is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. FullFocus is intended to be used with the interoperable components specified in the below Table.

Table: Interoperable components of FullFocus
<table>
<tr><th>Scanner Hardware</th><th>Scanner Output file format</th><th>Interoperable Displays</th></tr>
<tr><td>Leica Aperio GT 450 DX scanner</td><td>DICOM, SVS</td><td rowspan="2">Dell UP3017
Dell U3023E
Dell U3223QE
JVC-Kenwood JD-C240BN01A</td></tr>
<tr><td>Hamamatsu NanoZoomer S360MD Slide Scanner</td><td>NDPI</td></tr>
</table></td><td>The NanoZoomer S360MD Slide scanner system (“NanoZoomer System”) is an automated digital slide creation, viewing, and management system. The NanoZoomer System is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (“FFPE”) tissue. The NanoZoomer System is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The NanoZoomer System comprises the NanoZoomer S360MD Slide scanner, the NZViewMD Software and the JVC Kenwood JDC240BN01A display. The NanoZoomer System is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using NanoZoomer System.</td></tr>
<tr><td>Specimen Type</td><td>Digitized surgical pathology slides prepared from FFPE tissue</td><td>Same</td></tr>
<tr><td>Image file format</td><td>• SVS & DICOM - Aperio GT450 DX
• NDPI – Hamamatsu NanoZoomer S360MD Slide scanner</td><td>NDPI</td></tr>
<tr><td>Image Manipulation Functions</td><td>Panning, zooming, annotations, and measurements</td><td>The NZViewMD software provides the user with a continuous view across the XY plane of the WSI with the ability to: View images with continuous panning and zooming, Annotate and bookmark images, Track visited areas and a software only subsystem with functionality that includes the ability to: View images and patient data, Organize workload, Annotate, bookmark, and/or tag images, Manually score images, Invite and join others for a shared session annotations, Export images to a network server, Discrete Z-axis displacement</td></tr>
<tr><td>Type of Software</td><td>Internet browser-based application</td><td>PC-based installed application</td></tr>
</table>

Application		
Device Components	FullFocus	Scanner, NZViewMD, Display
End User's Interface	FullFocus	NZViewMD
Principle of Operation	After WSI images are successfully acquired by using Leica Aperio GT 450 DX scanner or Hamamatsu NanoZoomer S360MD Slide scanner, the WSI images are stored in the cloud. During review, the pathologist opens WSI images from storage, perform further QC and reads WSI images of the slides render a diagnosis.	The NanoZoomer S360MD Slide scanner system ("NanoZoomer System") is an automated digital slide creation, viewing, and management system. The NanoZoomer System is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalinfixed paraffin embedded ("FFPE") tissue. The NanoZoomer System is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The system's embedded image processing software is responsible for image acquisition and the processing of individual tiles prior to image composition or stitching. Hamamatsu's NZAcquireMD software organizes all WSI tiles into a single NDPi file, which is a proprietary file format. During the review, the pathologist opens the WSI on the NZViewMD software to render a diagnosis.
Image Storage	Images are stored in the cloud	Images are stored in the end-user provided image storage attached to the local network

Summary of Performance Testing Data

<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td>Pixel-wise comparison</td><td>Pixel-wise comparison study was conducted to compare images reproduced by FullFocus, version 2.29, and the comparators (the predicate device's image review manipulation software (IRMS, as defined in FDA guidance document, "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices" dated April 20, 2016") as described below for the same image file format generated from the same intended use scanner to validate identical image reproduction on the same intended displays.
<table>
<tr><th>Scanner</th><th>Image File Format</th><th>Subject Device (Viewer/Browser)</th><th>Comparator (Predicate device IRMS)</th><th>Displays</th></tr>
<tr><td rowspan="4">Leica Aperio GT450DX scanner</td><td rowspan="2">DICOM</td><td>FullFocus/Chrome</td><td>Sectra UniView/Chrome</td><td rowspan="5">Dell UP3017
Dell U3023E
Dell U3223QE
JVC-Kenwood JD-C240BN01A</td></tr>
<tr><td>FullFocus/Edge</td><td>Sectra UniView/Edge</td></tr>
<tr><td rowspan="2">SVS</td><td>FullFocus/Chrome</td><td>Aperio WebViewer DX/Chrome</td></tr>
<tr><td>FullFocus/Edge</td><td>Aperio WebViewer DX/Edge</td></tr>
<tr><td rowspan="2">Hamamatsu NanoZoomer S360MD Slide scanner</td><td rowspan="2">NDPI</td><td>FullFocus/Chrome</td><td>NZViewMD</td></tr>
<tr><td>FullFocus/Edge</td><td>NZViewMD</td></tr>
</table>
A total of 30 formalin-fixed paraffin-embedded (FFPE) tissue glass slides, representing a</td></tr>
</table>

<table>
<tr><td></td><td>range of human anatomical sites, were scanned at 40x magnification using both slide scanner systems. The slides scanned with the Leica Aperio GT450 DX scanner were saved in both DICOM and SVS formats, while the slides scanned with the Hamamatsu NanoZoomer S360MD Slide Scanner were saved in NDPI format. For each WSI, three regions of interest (ROIs) were identified to highlight relevant pathological features, as verified by a pathologist. Screenshots of these ROIs were captured at two magnification levels (10x and 40x) across multiple displays and browsers as specified in the above table. The testing process ensured comprehensive evaluation across display variations, with all image pairs registered and cropped for analysis. Every pixel of each screenshot was sampled to calculate the pixel-wise color difference using the CIEDE2000 (ΔE00) metric.
The acceptance criterion for this testing required that the 95th percentile of the pixel-wise color differences in any image pair across all required screenshots be less than 3.0 ΔE00.
Test results showed that the 95th percentile of pixelwise differences between FullFocus and the comparators were less than 3 CIEDE2000, indicating that their output images can be considered to be pixel-wise identical. Therefore, FullFocus has been found to visually adequately reproduce digital pathology images to human readers with respect to its intended use.</td></tr>
<tr><td>Turnaround time</td><td>The system requirements have been fulfilled:
• When selecting a case, it should not take longer than 10 seconds until the image is fully loaded.
• When panning and zooming the image it shall not take longer than 7 seconds until the image is fully loaded.</td></tr>
<tr><td>Measurements</td><td>Measurement accuracy has been verified using a test image containing objects with known sizes. FullFocus has been found to perform accurate measurements with respect to its intended use. See the overview of the test results below.
<table>
<tr><th>Description</th><th>Sample size</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td>Straight Line Measurement in Chrome and Edge browsers</td><td>1 Calibration Slide</td><td>The 1 mm measured line should match the reference value exactly 1 mm ± 0mm</td><td>All measurements compared to the reference were exactly 1 mm, with no error.</td></tr>
<tr><td>Area Measurement in Chrome and Edge browsers</td><td>1 Calibration Slide</td><td>The measured area must match the reference area exactly 0.2 x 0.2 mm for a total of 0.04 mm^2 ± 0 mm^2</td><td>All area measurements compared to the reference value were exactly 0.04mm^2, with no error.</td></tr>
<tr><td>Scalebar Measurement in Chrome and Edge browsers</td><td>1 Calibration Slide</td><td>2mm scalebar is accurate</td><td>All Tests Passed</td></tr>
</table></td></tr>
<tr><td>Human Factors Testing</td><td>Human factors study designed around critical user tasks and use scenarios performed by representative users were conducted for previously cleared FullFocus, version 1.2.1, in K201005, per FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices (2016)”. Human factors validation testing is not necessary as the user interface and workflow remain unchanged.</td></tr>
</table>

Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision of FullFocus to the predicate devices.