



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K253561

B Applicant

Leica Biosystems Imaging, Inc.

C Proprietary and Established Names

Aperio iQC DX Software

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SIX	Class II	21 CFR 864.3700 - Whole Slide Imaging System	PA - Pathology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Type of Test:

Software only device

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Aperio iQC DX Software is an artificial intelligence-based software intended to be used as an aid in the identification of artifacts in scanned whole slide images (WSIs) of hematoxylin and eosin

(H&E) and immunohistochemistry (IHC) stained, formalin-fixed paraffin embedded (FFPE) tissue that should undergo further evaluation for image quality prior to diagnostic review of the images by pathologists. Aperio iQC DX Software identifies the following artifacts:

- Digital artifacts: out of focus, image striping, missing and clipped tissue
- Slide preparation artifact: air bubbles
- Other artifact: pen marks

Aperio iQC DX Software outputs the following:

- Binary ‘artifact detected’ or ‘no artifact detected’ for air bubbles, image striping, missing and clipped tissue, out of focus, and pen marks,
- Overlays highlighting the location of air bubbles and out of focus artifacts only, and
- Bounding boxes for missing and clipped tissue artifacts.

Aperio iQC DX Software is intended to be used in conjunction with the complete in-house laboratory image quality control workflow. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images when using the Aperio iQC DX Software. Aperio iQC DX Software is not intended to be used for diagnosis, prognosis, or prediction of disease.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

Aperio iQC DX Software (Model:23iQCDXUS), version 1.0, is an Artificial Intelligence (AI) based software algorithm derived from deep learning convolutional neural networks. The Aperio iQC DX Software algorithm is locked; it is not a continuous learning (continual machine learning model) algorithm.

Aperio iQC DX Software utilizes scanned whole slide images (WSIs) as inputs from Aperio GT 450 DX and GT 180 DX scanners to identify the digital artifacts using four AI models which were developed and trained on WSIs of H&E and DAB (3,3'-diaminobenzidine) chromogen based IHC stained tissue slides originating from FFPE tissue sections. Aperio iQC DX Software generates two types of visualizations of the detected artifact regions as follows: a bounding box is provided for Missing and Clipped Tissue and overlays for Out of Focus and Air Bubble artifacts. Aperio iQC DX Software identifies the following artifacts: missing and clipped tissue, out of focus, image striping; slide preparation artifact: air bubbles, and pen marks on WSIs. It is used to augment the initial quality review performed by laboratory personnel prior to making the WSI available to the pathologist for diagnostic review. The final determination of whether the WSIs are sufficient for diagnostic review remains the responsibility of the pathologist and occurs outside of Aperio iQC DX Software.

Aperio iQC DX Software outputs the following:

- Binary ‘artifact detected’ or ‘no artifact detected’ for air bubbles, image striping, missing and clipped tissue, out of focus, and pen marks
- Overlays highlighting the location of air bubbles and out of focus artifacts only, and
- Bounding boxes for missing and clipped tissue artifacts

These outputs are displayed to the user in the Aperio iQC DX Dashboard (a browser-based user interface used only for non-diagnostic purposes).

Aperio iQC DX Software is operated as follows:

1. Copies of WSIs are sent to the customer’s dedicated image storage by the connected WSI system.
2. Once available, Aperio iQC DX Software automatically executes AI algorithms on the copies of the WSIs from the customer’s dedicated image storage.
3. For WSI, Aperio iQC DX Software outputs ‘artifact detected’ or ‘no artifact detected’ for each artifact. In addition, whenever out of focus or air bubble artifacts are detected, overlays indicating the presence of the artifact are available. For missing and clipped tissue, a bounding box is provided.
4. All findings are displayed to the user in the Aperio iQC DX Dashboard where the user (e.g., laboratory technicians) will perform image quality review and ‘accept’ or ‘reject’ the image and include comments for any rejection.

The intended use interoperable components of the Aperio iQC DX Software device are identified in Table 1 below.

Table 1: Intended Use Components

Component
Aperio GT 450 DX Scanner (cleared under K253554) Aperio GT 180 DX Scanner (cleared under K253554)
Aperio SAM DX Software (cleared under K253554)

Computer Environment/System Requirements for the Aperio iQC DX Software device are identified in Table 2 below.

Table 2: Customer Environment/System Requirements

Workstation Component	Specification
Computer System	RAM: 64 GB per scanner CPU: Intel Core i7 or higher, or AMD EPYC 9004 and 8004 Series
Web Browser	Google Chrome: 126 or later Microsoft Edge: 126 or later Firefox: 127 or later
Operating System	Linux Ubuntu 24.04 LTS or higher

Workstation Component	Specification
Network	Internet access At least 100 Mbps upload speed

B Instrument Description Information:

1. Instrument Name:
Aperio iQC DX Software
2. Specimen Identification:
Aperio iQC DX Software uses an image of the barcode on the slide for identification.
3. Specimen Sampling and Handling:
Specimen sampling and handling are performed upstream and independent of the use of the subject device. Specimen sampling includes biopsy or resection specimens which are processed using histology techniques. The FFPE tissue section is H&E or IHC stained. Digital images are then obtained from these glass slides using the intended use scanners specified in Table 1 above.
4. Calibration:
Aperio iQC DX Software is a software only device that does not require calibration.
5. Quality Control:
After evaluation and identification of artifacts in the scanned WSIs of the intended use slides by the Aperio iQC DX Software, any WSI with artifacts is reviewed by the appropriate laboratory personnel, and the subsequent corrective action depends on the type of artifact identified. For digital artifacts (e.g., out of focus, image striping, missing and clipped tissue), the affected slide(s) may be rescanned as needed; however, for histological artifacts (e.g., air bubbles), the physical glass slide(s) must first be reprocessed or otherwise corrected before rescanning.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Aperio GT 450 DX System

B Predicate 510(k) Number(s):

K253554

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253561 Subject Device	K253554 (Predicate Device)
Device Trade Name	Aperio iQC DX Software	Aperio GT 450 DX
General Device Characteristic Similarities		
Intended Use/Indications For Use	Aperio iQC DX Software is an artificial intelligence-based software intended to be used as an aid in the identification of artifacts in scanned whole slide images (WSIs) of hematoxylin and eosin (H&E) and immunohistochemistry (IHC) stained, formalin-fixed paraffin embedded (FFPE) tissue that should undergo further evaluation for image quality prior to diagnostic review of the images by pathologists. Aperio iQC DX Software identifies the following artifacts: • Digital artifacts: out of focus, image striping, missing and clipped tissue • Slide preparation artifact: air bubbles • Other artifact: pen marks Aperio iQC DX Software outputs the following: • Binary ‘artifact detected’ or ‘no artifact detected’ for air bubbles, image striping, missing and clipped tissue, out of focus, and pen marks, • Overlays highlighting the location of air bubbles and out of focus artifacts only, and • Bounding boxes for missing and clipped tissue artifacts. Aperio iQC DX Software is intended to be used in conjunction with the complete in-house laboratory image quality control workflow. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images when using the Aperio iQC DX Software. Aperio iQC DX Software is not intended to be used for diagnosis, prognosis, or prediction of disease.	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. The Aperio GT 450 DX is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. 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 the Aperio GT 450 DX.
Specimen Type	Formalin-Fixed Paraffin- Embedded (FFPE) specimen	Same
Tissue Finding	Automatic	Same

Image Storage	Images stored in the end-user- provided image storage on the local network.	Same
General Device Characteristic Differences		
Device Type	Artificial intelligence-based software application based on convolutional neural networks (CNNs)	Traditional image analysis software feature (Tissue Finder)
Auto QC during scanning	No	Yes
Viewer	N/A; images are viewed within the Aperio iQC DX dashboard (not for diagnostic use)	Aperio WebViewer DX
Compatible Display (Monitor)	Off-the-Shelf Monitor since this is not for diagnostic use.	Aperio WebViewer DX is intended for use with specific cleared intended use interoperable displays.
Image Manipulation Functions	Panning/Zooming (non- continuous)	Aperio WebViewer DX permits continuous panning/zooming, ability to compare images, annotations, digital bookmarks, measurements (distance), gamma function
Operational Mode	Image QC; not to be used to diagnose disease	Diagnostic device
Hardware Inputs	Aperio GT 450 DX and Aperio GT 180 DX • Bounding Box • Macro image • Scan data • Scanner configurations (rack position, rescan capability, scanner identifiers) • Hash files	Tissue finder receives the following from the scanner: • Config Values • Macro Image • Dirt Image
Output	• Binary artifact detected or no artifact detected • Overlays (air bubbles, out of focus) • Bounding Box (missing and clipped tissue)	Bounding Box indicating where the scan area (Tissue Finder) and WSI

VI Standards/Guidance Documents Referenced:

1. Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices (February 2016).
2. Guidance for Industry and Food and Drug Administration Staff: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June 2025).
3. Guidance for Food and Drug Administration Staff: Content of Premarket Submissions for Device Software Functions (June 2023).

VII Aperio iQC DX Software Model Development

Aperio iQC DX Software development was performed on training, tuning, and test datasets. Each dataset contained slides from unique patients ensuring that training, tuning and test datasets

do not have any WSIs in common. WSIs were labeled as artifact present or ‘none’. These datasets were completely independent from the validation dataset.

Table 3: Data Split for Training, Tuning and Test Sets, Algorithm Development

Training Dataset	Tuning Dataset	Test Dataset
De-identified slides were procured from external vendors or prepared at an internal site and scanned with Aperio GT 450 scanners. Number of slide images: 12,278 (5158 H&E WSIs, 7127 IHC WSIs)	De-identified slides were procured from external vendors or prepared at an internal site and scanned with Aperio GT 450 scanners. Number of slide images: 2,450 (1455 H&E WSIs, 995 IHC WSIs)	De-identified slides were procured from external vendors or prepared at an internal site and scanned with Aperio GT 450 scanners. Number of slide images: 4,752 (1828 H&E WSIs, 2924 IHC WSIs)

Demographics and geographic considerations were not observed as the regional variation in tissue morphology was not expected to influence artifact presence or detection.

VIII Performance Characteristics (if/when applicable):

Performance testing was conducted with the Aperio iQC DX Software which included: algorithm accuracy study, algorithm localization accuracy study and precision studies.

1. Algorithm Accuracy Study

The algorithm accuracy study assessed the performance of the device to detect and localize digital and histological artifacts, including missing/clipped tissue, image striping, out of focus areas, air bubbles, and pen marks when single and multiple artifacts were present. The study included a diverse dataset of WSIs across multiple intended use tissue types, staining methods (H&E and IHC) and both the intended use scanners (Aperio GT 450 DX and GT 180 DX). This dataset was independent of the training dataset.

The evaluation was conducted by comparing Aperio iQC DX Software’s results against the ground truth annotations determined by qualified experts.

Device accuracy was tested for single and multiple artifacts. For single artifacts, WSIs were created using the Aperio GT 450 DX scanner and the Aperio GT 180 DX scanner.

The Aperio GT 450 DX scanner dataset consisted of the following: Missing and Clipped Tissue - 2568 WSIs (1284 positive, 1284 negative), Image Striping - 2222 WSIs (1167 positive, 1055 negative), Out of Focus - 924 WSIs (221 positive, 703 negative), Air Bubbles - 2134 (883 positive, 1251 negative) , and Pen Marks - 2478 WSIs (1376 positive, 1102 negative).

Study results are provided in the tables below.

Table 4: Performance data of Aperio iQC DX using Aperio GT 450 DX scanner by each artifact independently

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	93.73	(92.73, 94.60)	94.78	(93.42, 95.87)	92.68	(91.12, 93.98)
Image Striping	99.82	(99.54, 99.93)	99.74	(99.24, 99.91)	99.91	(99.47, 99.98)
Out of Focus	97.29	(96.04, 98.16)	93.67	(89.65, 96.19)	98.44	(97.22, 99.12)
Air Bubble	95.60	(94.64, 96.39)	93.20	(91.35, 94.68)	97.28	(96.22, 98.05)
Pen Mark	99.19	(98.75, 99.47)	99.13	(98.48, 99.50)	99.27	(98.57, 99.63)

Table 5: Performance of Aperio iQC DX Software using Aperio GT 450 DX Scanner and H&E-stained slides by evaluating each artifact independently

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	94.76	(93.05, 96.06)	95.80	(93.47, 97.33)	93.71	(91.00, 95.64)
Image Striping	100	(99.42,100.00)	100	(99.07,100.00)	100	(98.50,100.00)
Out of Focus	96.62	(94.41,97.98)	93	(86.25,96.57)	97.77	(95.47,98.92)
Air Bubble	98.40	(97.16,99.10)	99.61	(97.82,99.93)	97.69	(95.80,98.74)
Pen Mark	99.14	(98.31,99.56)	99.06	(97.82,99.60)	99.26	(97.85,99.75)

Table 6: Performance of Aperio iQC DX Software using Aperio GT 450 DX Scanner and IHC-stained slides by evaluating each artifact independently

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	93.22	(91.93, 94.31)	94.27	(92.50, 95.64)	92.16	(90.17, 93.78)
Image Striping	99.74	(99.34,99.90)	99.60	(98.84,99.86)	99.88	(99.31,99.98)
Out of Focus	97.84	(96.18,98.79)	94.21	(88.53,97.17)	98.97	(97.38,99.60)
Air Bubble	94.26	(92.94,95.35)	90.61	(88.08,92.65)	97.07	(95.68,98.02)
Pen Mark	99.22	(98.64,99.55)	99.17	(98.30,99.60)	99.28	(98.33,99.69)

The Aperio GT 180 DX scanner dataset consisted of the following: Missing and Clipped Tissue - 576 WSIs (288 positive, 288 negative), Image Striping - 439 WSIs (158 positive, 281 negative), Out of Focus - 486 WSIs (243 positive, 243 negative), Air Bubbles - 645 (190 positive, 455 negative), and Pen Marks - 424 WSIs (142 positive, 282 negative). Study results are provided in the tables below.

Table 7: Validation performance of Aperio iQC DX in Aperio GT 180 DX scanner by evaluating each artifact independently

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	93.40	(91.07, 95.15)	94.10	(90.75, 96.28)	92.71	(89.11, 95.18)
Image Striping	99.77	(98.72, 99.96)	99.37	(96.51, 99.89)	100	(98.65, 100)
Out of Focus	93.62	(91.09, 95.47)	92.18	(88.11, 94.94)	95.06	(91.57, 97.15)
Air Bubble	96.43	(94.70, 97.61)	93.16	(88.65, 95.96)	97.80	(97.51, 99.55)
Pen Mark	99.06	(97.60, 99.63)	99.30	(96.13, 99.88)	98.94	(96.93, 99.64)

Table 8: Performance of Aperio iQC DX Software using Aperio GT 180 DX scanner and H&E-stained slides by evaluating each artifact independently

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	94.27	(90.03,96.77)	95.83	(89.77,98.37)	92.71	(85.71,96.42)
Image Striping	100	(97.37,100.00)	100	(92.29,100.00)	100	(96.15,100.00)
Out of Focus	96.10	(92.76,97.93)	97.89	(93.98,99.28)	93.26	(86.07,96.87)
Air Bubble	97.51	(94.31,98.93)	95.65	(87.98,98.51)	98.48	(94.64,99.58)
Pen Mark	99.31	(96.18,99.88)	100	(92.59,100.00)	98.96	(94.34,99.82)

Table 9: Performance of Aperio iQC DX Software using Aperio GT 180 DX Scanner and IHC-stained slides by evaluating each artifact independently

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	92.97	(89.96,95.12)	93.23	(88.76,96.00)	92.71	(88.14,95.61)
Image Striping	99.66	(98.11,99.94)	99.11	(95.12,99.84)	100	(97.97,100.00)
Out of Focus	91.37	(87.28,94.23)	84.16	(75.81,90.01)	96.10	(91.76,98.20)
Air Bubble	95.95	(93.69,97.42)	91.74	(85.46,95.45)	97.52	(95.19,98.74)
Pen Mark	98.93	(96.90,99.64)	98.94	(94.22,99.81)	98.92	(96.16,99.70)

To evaluate multiple artifacts, WSIs were created using the GT 450 DX scanner to demonstrate performance for the detection of each artifact when multiple artifacts are present. Two data sets were used for multiple artifact testing. The first dataset was used for evaluating performance of air bubbles, image striping, out of focus, and pen marks and consisted of: 522 WSIs positive for multiple artifacts (241 doubles, 106 triples, 175

quadruple). The second dataset was used for evaluating performance of missing and clipped tissue and consisted of: 505 WSIs positive for multiple artifacts (172 doubles, 132 triples, 138 quadruple, 63 quintuple). Total positive and negative counts for multiple artifacts were as follows: Missing and Clipped tissue (305 positive, 200 negative), Image Striping (440 positive, 82 negative), Out of Focus (368 positive, 154 negative), Air Bubbles (308 positive, 214 negative), and Pen Marks (384 positive, 138 negative).

Table 10: Overall performance of Aperio iQC DX Software using Aperio GT 450 DX Scanner for multiple artifacts

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	93.27	(90.74, 95.14)	93.11	(89.70, 95.45)	93.50	(89.20, 96.16)
Image Striping	99.43	(98.33, 99.81)	99.32	(98.02, 99.77)	100	(95.52, 100)
Out of Focus	95.79	(93.71, 97.20)	96.47	(94.05, 97.93)	94.16	(89.27, 96.90)
Air Bubble	95.40	(93.25, 96.90)	92.53	(89.04, 94.97)	99.53	(97.40, 99.92)
Pen Mark	97.70	(96.02, 98.68)	99.48	(98.12, 99.86)	92.75	(87.17, 96.01)

Table 11: Performance of Aperio iQC DX Software using Aperio GT 450 DX scanner and H&E-stained slides for evaluating multiple artifacts

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	94.67	(90.91, 96.92)	97.14	(92.88, 98.88)	90.59	(82.51, 95.15)
Image Striping	99.22	(97.19, 99.78)	99.06	(96.64, 99.74)	100	(91.62, 100.00)
Out of Focus	95.69	(92.44, 97.57)	95.60	(91.57, 97.76)	95.89	(88.60, 98.59)
Air Bubble	96.86	(93.93, 98.40)	95.68	(91.35, 97.89)	98.92	(94.16, 99.81)
Pen Mark	96.08	(92.93, 97.86)	100	(97.78, 100.00)	88.37	(79.90, 93.56)

Table 12: Performance of Aperio iQC DX Software using Aperio GT 450 DX scanner and IHC-stained slides for evaluating multiple artifact

	Accuracy (%)	95% CI Accuracy (%)	Sensitivity (%)	95% CI Sensitivity (%)	Specificity (%)	95% CI Specificity (%)
Missing and Clipped Tissue	92.14	(88.39, 94.75)	89.70	(84.12, 93.47)	95.65	(90.22, 98.13)
Image Striping	99.63	(97.91, 99.93)	99.56	(97.55, 99.92)	100	(91.24, 100.00)
Out of Focus	95.88	(92.77, 97.68)	97.31	(93.86, 98.85)	92.59	(84.77, 96.56)
Air Bubble	94.01	(90.49, 96.28)	89.04	(82.94, 93.14)	100	(96.92, 100.00)
Pen Mark	99.25	(97.31, 99.79)	99.07	(96.67, 99.74)	100	(93.12, 100.00)

The results of the accuracy study demonstrate that overall performance of Aperio iQC DX Software achieved sensitivity and specificity of $\geq 90\%$ and $\geq 85\%$ for the lower bound of corresponding 95% CI for single and multiple artifact detection, for the analysis of the combined H&E and IHC dataset.

2. **Localization Accuracy**

To evaluate the performance of the device in localization of Missing and Clipped Tissue, the overlap of Aperio iQC DX Software's predicted bounding box and the ground truth bounding box was calculated using intersection over union (IoU) ratio. The slide level average of sensitivity and specificity were reported. IoU was calculated for each WSI, then averaged across the dataset and reported.

To evaluate the performance in Out of Focus and Air Bubble localization, the pixel-level sensitivity and specificity for each WSI were computed by comparing the predicted artifact regions against the ground truth artifact regions. The ground truth was established through annotations performed by qualified expert annotators. For Missing and Clipped Tissue, annotators drew bounding boxes encompassing all visible tissue in the macro image, and the ground truth label was determined by comparing the annotated bounding box against the scanner's scanned region. For Out of Focus and Air Bubble localization, annotators placed positive and negative non-overlapping bounding boxes on representative tissue regions with and without the respective artifacts. A second annotator independently reviewed all annotations for quality control purposes, with a third-party arbiter consulted in cases of discordance. Sensitivity and specificity were calculated for each WSI, then averaged across the dataset and reported.

The dataset for localization performance included 1,988 WSIs with missing and clipped tissue, 67 WSIs with out of focus artifacts and 60 WSIs with air bubble artifacts. Study results are shown in the Tables below.

The results of the localization accuracy study demonstrate that Aperio iQC DX Software achieved $\geq 90\%$ of WSIs with $\text{IoU} \geq 70\%$ for missing and clipped tissue artifact detection and achieved $\geq 90\%$ in sensitivity and specificity for out of focus and air bubble artifact detection.

Table 13: Localization performance in Missing and Clipped Tissue detection

	Average IoU	Number of WSIs achieve $\text{IoU} \geq 70\%$	Ratio of the WSIs achieve $\text{IoU} \geq 70\%$
Missing and Clipped Tissue	88.41%	1804	90.74%

Table 14: Localization performance in Out of Focus and Air Bubble detection

	Localization Sensitivity (%)	95% CI Sensitivity (%)	Localization Specificity (%)	95% CI Specificity (%)
Out of Focus	96.99	(95.44%, 98.02%)	99.72	(99.02%, 99.92%)
Air Bubble	91.29	(88.75%, 93.30%)	96.01	(94.12%, 97.31%)

3. **Precision**

The precision (repeatability and reproducibility) testing was conducted to evaluate the Aperio iQC DX Software using H&E and IHC WSIs generated from the Aperio GT 450 DX Scanner and Aperio GT 180 DX Scanner.

The dataset for H&E comprised of 63 whole slide images (WSIs) per scanner:

- 3 WSIs per artifact across five artifacts (positive cases)
- 3 WSIs containing multiple artifacts (positive cases)
- 3 WSIs that contain no artifacts (negative cases)

Each WSI was rotated in two different orientations generating three replicates per WSI. The dataset for IHC was comprised of 63 whole slide images (WSIs) per scanner:

- 3 WSIs per artifact across five artifacts (positive cases)
- 3 WSIs containing multiple artifacts (positive cases)
- 3 WSIs that contain no artifacts (negative cases)

Each WSI was rotated in two different orientations generating three replicates per WSI. Ground truth was established through annotations performed by a group of qualified annotators.

Evaluation Method: To assess precision under variable conditions, each WSI was subjected to two deterministic image orientations, generating three replicates per WSI, for a total of nine replicate evaluations per artifact category.

The validation data demonstrates that Aperio iQC DX Software achieves 100% for correct call for all types of cases. Results are provided in the tables below.

Table 15: Precision performance under variable conditions for H&E WSIs using GT 450 DX Scanner

Type of Cases	Type of Artifacts	#WSIs	#Replicates /WSI	#Total Replicates	%Correct Call	95%CI (%) *
Positive Cases-Single Artifact	Missing and Clipped Tissue	3	3	9	100%	(70.1%, 100%)
	Image Striping	3	3	9	100%	(70.1%, 100%)
	Out of Focus	3	3	9	100%	(70.1%, 100%)
	Air Bubble	3	3	9	100%	(70.1%, 100%)
	Pen Mark	3	3	9	100%	(70.1%, 100%)
Positive Cases-Multiple Artifacts	Multiple Artifacts	3	3	9	100%	(70.1%, 100%)
Negative Cases	No Artifact	3	3	9	100%	(70.1%, 100%)
Overall				63	100%	(94.3%, 100%)

*95%CI was calculated by Wilson score method

Table 16: Precision performance under variable conditions for H&E WSIs using GT 180 DX Scanner

Type of Cases	Type of Artifacts	#WSIs	#Replicates /WSI	#Total Replicates	%Correct Call	95%CI (%) *
Positive Cases-Single Artifact	Missing and Clipped Tissue	3	3	9	100%	(70.1%, 100%)
	Image Striping	3	3	9	100%	(70.1%, 100%)
	Out of Focus	3	3	9	100%	(70.1%, 100%)
	Air Bubble	3	3	9	100%	(70.1%, 100%)
	Pen Mark	3	3	9	100%	(70.1%, 100%)
Positive Cases-Multiple Artifacts	Multiple Artifacts	3	3	9	100%	(70.1%, 100%)
Negative Cases	No Artifact	3	3	9	100%	(70.1%, 100%)
Overall				63	100%	(94.3%, 100%)

*95%CI was calculated by Wilson score method

Table 17: Precision performance under variable conditions for IHC WSIs using GT 450 DX Scanner

Type of Cases	Type of Artifacts	#WSIs	#Replicates /WSI	#Total Replicates	%Correct Call	95%CI (%) *
Positive Cases-Single Artifact	Missing and Clipped Tissue	3	3	9	100%	(70.1%, 100%)
	Image Striping	3	3	9	100%	(70.1%, 100%)
	Out of Focus	3	3	9	100%	(70.1%, 100%)
	Air Bubble	3	3	9	100%	(70.1%, 100%)
	Pen Mark	3	3	9	100%	(70.1%, 100%)
Positive Cases-Multiple Artifacts	Multiple Artifacts	3	3	9	100%	(70.1%, 100%)
Negative Cases	No Artifact	3	3	9	100%	(70.1%, 100%)
Overall				63	100%	(94.3%, 100%)

*95%CI was calculated by Wilson score method

Table 18: Precision performance under variable conditions for IHC WSIs using GT 180 DX Scanner

Type of Cases	Type of Artifacts	#WSIs	#Replicates /WSI	#Total Replicates	%Correct Call	95%CI (%) *
Positive Cases-Single Artifact	Missing and Clipped Tissue	3	3	9	100%	(70.1%, 100%)
	Image Striping	3	3	9	100%	(70.1%, 100%)
	Out of Focus	3	3	9	100%	(70.1%, 100%)
	Air Bubble	3	3	9	100%	(70.1%, 100%)
	Pen Mark	3	3	9	100%	(70.1%, 100%)
Positive Cases-Multiple Artifacts	Multiple Artifacts	3	3	9	100%	(70.1%, 100%)
Negative Cases	No Artifact	3	3	9	100%	(70.1%, 100%)
Overall				63	100%	(94.3%, 100%)

*95%CI was calculated by Wilson score method

IX Other Supportive Instrument Performance Characteristics Data:

Human Factors and Usability testing was completed, and documentation was provided in the submission as recommended in Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices (February 2016).

Software and cybersecurity documentation was reviewed and found to be acceptable.

X Proposed Labeling:

The labeling supports the finding of substantial equivalence for Aperio iQC DX Software device.

XI Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.