

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

k141109

**B. Purpose for Submission:**

Addition of the AT Turbo and CS2 scanner models to the cleared Aperio ScanScope® XT System for scoring ER, PR and HER2 immunohistochemically stained slides by the image analysis algorithm method.

**C. Manufacturer and Instrument Name:**

Leica Biosystems Imaging, Inc., Aperio ePathology eIHC IVD System, AT Turbo and CS2 models

**D. Type of Test or Tests Performed:**

Computer-assisted image analysis algorithm for scoring immunohistochemically stained HER2/neu slides, estrogen receptor (ER)/progesterone receptor (PR) slides.. The image analysis algorithm scoring is confirmed by the pathologist before reporting the scores.

**E. System Descriptions:**

1. Device Description:

The Aperio ePathology eIHC IVD System is a closed system comprised of a ScanScope® digital slide scanner instrument (either the ScanScope AT Turbo or the ScanScope CS2) and eSlide Manager software, ImageScope software and Image Analysis Algorithms, as applicable. The Aperio ePathology eIHC IVD System is an automated digital slide creation, management, viewing and analysis system. The system is comprised of a slide scanner instrument and a computer executing eSlideManager, ImageScope and Image Analysis Algorithm software. The system capabilities include digitizing immunohistochemically stained slides, storing and managing the resulting digital slide images, retrieving and displaying digital slides, providing tools for annotating digital slides and entering and editing data associated with digital slides, and tools for image analysis of the regions that pathologists select on the digital slide images.

2. Principles of Operation:

Glass slides are digitized by an image acquisition system that provides digital slide images of the immunohistochemically stained slides; the image acquisition system provides support for patient / slide identification, slide loading, calibration, tissue identification, focusing and digital image storage and management. Pathologists select

regions on the digital slide images that will be automatically analyzed by an image analysis algorithm for HER2 or ER/PR (i.e., HER2 or ER/PR Image Analysis). The regions on the digital slide images selected by pathologists for image analysis should be representative for the entire tumor.

The HER2 Image Analysis algorithm detects the membrane staining for the individual tumor cells in the selected regions and quantifies the intensity and completeness of the membrane staining. Tumor cells are individually classified as 0, 1+, 2+, and 3+ based on their membrane staining intensity and completeness. The HER2 score is then calculated based on the percentages of 0, 1+, 2+, and 3+ cells according to the HER2 scoring scheme. A markup image highlights the detected cell features (black = nuclei and membrane) and the membrane staining which is color-coded according to the cell classification (blue = 0, yellow = 1+, orange = 2+, red = 3+). The pathologist is then provided with HER2 score and the percentages of 0, 1+, 2+, and 3+ cells. The pathologist makes the final interpretation based on both the qualitative and quantitative information and should follow all appropriate instructions in the Dako Hercep Test™ product insert

The ER/PR image analysis algorithms use color, intensity, size, pattern and shape information to detect, count, and classify cells of interest and determine a score that correlates with the score the pathologists provide. The image analysis algorithm reports the percentage of positive nuclei and average intensity score of 0, 1+, 2+ or 3+ for each slide. The pathologist makes the final interpretation based on the percent positivity of tumor nuclei and/or staining intensity according to the laboratory's established interpretation criteria.

3. Modes of Operation:

Semi-automated computer-assisted scoring of IHC HER2, ER or PR stained slide images performed by Image Analysis Applications with manual verification by the pathologist.

4. Specimen Identification:

Glass slides are identified by barcode label

5. Specimen Sampling and Handling:

The Autoloader component of the ScanScope® AT Turbo instrument is responsible for storing slides to be scanned, and contains a mechanism for mounting the current slide to be processed on the scanning stage. The slide autoloader is an assembly within the ScanScope AT Turbo that can hold up to 400 slides.

The ScanScope® CS2 has no Autoloader. The CS2 has a five slide capacity tray that can be inserted by the operator into the system.

6. Calibration:

The scanner is calibrated and verified at the factory before shipment. No further manual calibration or verification is required by the customer. Annual preventive maintenance, performed by Leica Biosystems Imaging Technical Services, is recommended to make sure the scanner is operating correctly. The scanner provides automatic calibration and verification every time a slide is scanned by performing prescan calibration during the scan.

7. Quality Control:

The pathologist must verify that the eSlides are of sufficient quality to perform his or her task. The pathologist should review the quality of the scanning by evaluating that the entire tissue sample is scanned and in focus. Positive and negative control slides are also scanned along with the patient slides which are reviewed by the pathologist before scoring.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes  or No

**F. Regulatory Information:**

1. Regulation section:

21 CFR §864.1860 Immunohistochemistry reagents and kits

2. Classification:

II

3. Product code:

NOT, NQN

4. Panel:

Pathology (88)

**G. Intended Use:**

1. Indication(s) for Use:

- **HER2 Image Analysis**

The Aperio ePathology eIHC IVD System is an automated digital slide creation, management, viewing and analysis system. It is intended for in vitro diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest based on particular color, intensity, size, pattern and shape.

The IHC HER2 Image Analysis application is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in formalin-fixed, paraffin-embedded neoplastic tissue.

The IHC HER2 Image Analysis application is intended for use as an accessory to the Dako HercepTest™ to aid in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in formalin-fixed, paraffin-embedded neoplastic tissue. When used with the Dako HercepTest™, it is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered.

Note: The IHC HER2 Image Analysis application is an adjunctive computer-assisted methodology to assist the reproducibility of a qualified pathologist in the acquisition and measurement of images from microscope slides of breast cancer specimens stained for the presence of HER-2 receptor protein. The IHC HER2 Image Analysis application is intended to be used on images viewed on a computer monitor. The accuracy of the test result depends upon the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for the Dako HercepTest™ to assure the validity of the IHC HER2 Image Analysis application assisted HER-2/neu score. The actual correlation of the Dako HercepTest™ to Herceptin® clinical outcome has not been established.

- **ER/PR Image Analysis**

The Aperio ePathology eIHC IVD System is an automated digital slide creation, management, viewing and analysis system. It is intended for in vitro diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest based on particular color, intensity, size, pattern and shape.

The IHC ER Image Analysis application is intended for use as an aid to the pathologist in the detection and quantitative measurement of ER (Estrogen Receptor) in formalin-fixed paraffin-embedded neoplastic tissue.

The IHC PR Image Analysis application is intended for use as an aid to the pathologist in the detection and quantitation measurement of PR (Progesterone Receptor) in formalin-fixed, paraffin-embedded neoplastic tissue.

It is indicated for use as an aid in the management, prognosis, and prediction of

therapy outcomes of breast cancer.

Note: The IHC ER and PR Image Analysis applications are an adjunctive computer-assisted methodology to assist the reproducibility of a qualified pathologist in the acquisition and measurement of images from microscope slides of breast cancer specimens stained for the presence of estrogen and progesterone receptor proteins. The IHC ER and PR Image Analysis applications are intended to be used on images viewed on a computer monitor. The accuracy of the test result depends upon the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for the ER and PR reagent/kit used to assure the validity of the IHC ER and PR Image Analysis application assisted scores.

2. Special Conditions for Use Statement(s):

For prescription use only

Indicated for use with slides stained on the Dako Autostainer??

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:  
ScanScope® System XT; k071128, k073677
2. Comparison with Predicate Device:

<b>Similarities and Differences</b>		
Item	Aperio ScanScope® XT System (Predicate)	Aperio ePathology eIHC IVD ScanScope AT Turbo and CS2 System
Intended Use/ Indications for Use	<p>The ScanScope System is an automated digital slide creation, management, viewing and analysis system. It is intended for in vitro diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest and shape.</p> <p>The IHC HER2 Image Analysis application (k071128) is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in</p>	Same

	<p>formalin-fixed, paraffin-embedded neoplastic tissue. The IHC HER2 Image Analysis application is intended for use as an accessory to the Dako HercepTest™ to aid in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in formalin-fixed, paraffin-embedded neoplastic tissue. When used with the Dako HercepTest™, it is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN® (Trastuzumab) treatment is being considered.</p> <p>The IHC ER Image Analysis application (k073677) is intended for use as an aid to the pathologist in the detection and quantitative measurement of ER (Estrogen Receptor) in formalin-fixed paraffin-embedded neoplastic tissue. The IHC PR Image Analysis application (k073677) is intended for use as an aid to the pathologist in the detection and quantitation measurement of PR (Progesterone Receptor) in formalin-fixed, paraffin-embedded neoplastic tissue. It is indicated for use as an aid in the management, prognosis, and prediction of therapy outcomes of breast cancer.</p>	
Specimen Type	Formalin-fixed, paraffin-embedded breast tissue specimens stained by immunohistochemistry	Same
Assay Used	<p>HER2: Dako HercepTest®</p> <p>ER: Dako Mouse Anti- Human Estrogen Receptor <math>\alpha</math> (Clone 1D5)</p> <p>PR: Dako Monoclonal Mouse Anti- Human Progesterone Receptor (Clone PgR 636)</p>	Same
Method of Interpretation	Pathologists select regions on the digital slide images that will be automatically analyzed by an image analysis algorithm for HER2 or ER/PR (i.e., HER2 or	Same

	ER/PR Image Analysis)	
DeviceComponents	System components consist of an automated digital microscope slide scanner, computer, color monitor, keyboard, image analysis software and digital pathology information management software	Same as predicate device with the exception of the following component updates: <ul style="list-style-type: none"> <li>• Slide Autoloader</li> <li>• Stages</li> <li>• Macro and Area Camera</li> <li>• Motion Control</li> <li>• Controller Software</li> <li>• Console Software</li> <li>• eSlide Manager Software</li> </ul>
Image Acquisition	Slide scanner based on line scanning technology	Same

**I. Special Control/Guidance Document Referenced (if applicable):**

None

**J. Performance Characteristics:**

1. Analytical Performance:

The performance of the ScanScope AT Turbo and CS2 models were evaluated for 1) system accuracy (method comparison) 2) inter-system precision and 3) intra-system precision. The performance studies were conducted using three (3) ScanScope AT Turbo systems, three (3) ScanScope CS2 systems (Candidate Devices) and one (1) of the original FDA cleared ScanScope XT systems (Predicate Device). Two board certified pathologists participated in the accuracy studies, and provided the annotations that were used in the precision studies. All study scanning was completed by a qualified scanning professional in a simulated laboratory environment.

The sample sizes for the Method Comparison and Precision Studies were based on the number of samples required to obtain the appropriate confidence in the data.

*a. Accuracy:*

The performance of the ScanScope AT Turbo and CS2 models were evaluated in comparison with the predicate device ScanScope XT systems using malignant breast cancer samples. The slides were scanned and analyzed by the predicate or ScanScope AT Turbo or CS2 models. Board certified pathologists provided the annotations. The data was recorded into contingency tables, and further analyzed for statistical significance based on the pre-established acceptance criteria. For the HER2 Method Comparison Study, 120 slides were obtained for the study, however 1 of the slide was removed for not having a malignant tumor yielding a total sample size of n = 119. The results are shown in Table 1.

**Table 1:** Method comparison contingency table for HER2 distribution between the ScanScope XT (Predicate Device), the ScanScope AT Turbo, and the Scanscope CS2 (Candidate Devices).

		Scanscope AT Turbo			Scanscope CS2		
		0/1+	2+	3+	0/1+	2+	3+
Scanscope XT	0/1+	31	0	0	31	0	0
	2+	3	29	5	1	30	6
	3+	0	3	48	0	2	49
	Total	34	32	53	32	32	55
	PA	90.70%			92.40%		
95% CI	(84.1, 95.3)			(86.1, 96.5)			
PPA	96.60%			98.90%			
95% CI	(90.4, 99.3)			(93.8, 99.9)			
NPA	100%			100%			
95% CI	(88.8, 100)			(88.8, 100)			

For the ER Method Comparison Study, 120 slides were obtained for the study, however 2 of the slides were removed for not having a malignant tumor yielding a total sample size of n = 118. The results are shown in Table 2.

**Table 2:** Method comparison contingency table for ER distribution at two different percent positive thresholds between the ScanScope XT (Predicate Device), the ScanScope AT Turbo, and the Scanscope CS2 (Candidate Devices).

		Scanscope AT Turbo				Scanscope CS2			
		1% cutoff		10% cutoff		1% cutoff		10% cutoff	
		<1%	1-100%	0-10%	11-100%	<1%	1-100%	0-10%	11-100%
Scanscope XT	<1%	45	2			42	5		
	1-100%	3	68			5	66		
	0-10%			59	2			59	2
	11-100%			1	56			1	56
	PA	95.80%		97.50%		91.50%		97.50%	
95% CI	(90.4, 98.6)		(92.8, 99.5)		(85.0, 95.9)		(92.8, 99.5)		
PPA	95.80%		98.20%		93%		98.20%		
95% CI	(88.1, 99.1)		(90.6, 99.9)		(84.3, 97.7)		(90.6, 99.9)		
NPA	95.70%		96.70%		89.40%		96.70%		
95% CI	(85.5, 99.5)		(88.7, 99.6)		(76.9, 96.5)		(88.7, 99.6)		

For the PR Method Comparison Study, 120 cases were obtained and included in the study (n = 120). The results are shown in Table 3.

**Table 3:** Method comparison contingency table for PR distribution at two different percent positive thresholds between the ScanScope XT (Predicate Device), the ScanScope AT Turbo, and the Scanscope CS2 (Candidate Devices).

Scanscope XT		Scanscope AT Turbo				Scanscope CS2			
		1% cutoff		10% cutoff		1% cutoff		10% cutoff	
		<1%	1-100%	0-10%	11-100%	<1%	1-100%	0-10%	11-100%
<1%	44	0			44	0			
1-100%	1	75			1	75			
0-10%			53	0			51	2	
11-100%			1	66			1	66	
PA 95% CI	99.20% (95.4, 99.9)		99.20% (95.4, 99.98)		99.20% (95.4, 99.9)		97.50% (92.9, 99.5)		
PPA 95% CI	98.70% (92.9, 99.9)		98.50% (92.0, 99.9)		99% (92.9, 99.9)		98.50% (92.0, 99.6)		
NPA 95% CI	100% (92.0, 100)		100% (93.3, 100)		100% (92.0, 100)		96.20% (87.0, 99.5)		

*b. Precision/Reproducibility:*

For the ScanScope AT Turbo HER2 Precision Studies, 40 slides were obtained, however 1 of the slides was removed for not having visible tumor on the slide yielding a sample size of n = 39. The results are shown in Table 4 and Table 5.

**Table 4:** Inter-system precision contingency tables for HER2 distribution in three ScanScope AT Turbo devices

Scanscope AT Turbo		Scanscope AT Turbo								
		System 2			System 3			System 3		
		0/1+	2+	3+	0/1+	2+	3+	0/1+	2+	3+
System 1	0/1+	10	0	0	10	0	0			
	2+	0	7	0	0	7	0			
	3+	0	0	22	0	0	22			
System 2	0/1+							10	0	0
	2+							0	7	0
	3+							0	0	22
PA 95% CI	100% (91.0, 100)			100% (91.0, 100)			100% (91.0, 100)			

**Table 5:** Intra-system precision contingency tables for HER2 distribution in three scans from the same ScanScope AT Turbo device

Scanscope AT Turbo		Scanscope AT Turbo								
		Run 2			Run 3			Run 3		
		0/1+	2+	3+	0/1+	2+	3+	0/1+	2+	3+
Run 1	0/1+	10	0	0	10	0	0			
	2+	0	7	0	0	7	0			
	3+	0	0	22	0	0	22			
Run 2	0/1+							10	0	0
	2+							0	7	0
	3+							0	0	22
PA 95% CI		100% (91.0, 100)			100% (91.0, 100)			100% (91.0, 100)		

The ScanScope CS2 HER2 Precision studies included 40 slides (n =40). The results are shown in Table 6 and Table 7.

**Table 6:** Inter-system precision contingency tables for HER2 distribution in three ScanScope CS2 devices

Scanscope CS2		Scanscope CS2								
		System 2			System 3			System 3		
		0/1+	2+	3+	0/1+	2+	3+	0/1+	2+	3+
System 1	0/1+	9	1	0	10	0	0			
	2+	0	14	0	0	14	1			
	3+	0	0	16	0	0	15			
System 2	0/1+							9	1	0
	2+							0	14	1
	3+							0	0	15
PA 95% CI		97.5% (86.8, 99.9)			97.5% (86.8, 99.9)			95% (83.1, 99.4)		

**Table 7:** Intra-system precision contingency tables for HER2 distribution in three scans from the same ScanScope CS2 device

Scanscope CS2		Scanscope CS2								
		Run 2			Run 3			Run 3		
		0/1+	2+	3+	0/1+	2+	3+	0/1+	2+	3+
Run1	0/1+	10	0	0	10	0	0			
	2+	0	14	0	0	14	0			
	3+	0	1	15	0	0	16			
Run2	0/1+							10	0	0
	2+							0	14	0
	3+							0	1	15
PA 95% CI		97.5% (86.8, 99.9)			100% (91.2, 100)			97.5% (86.8, 99.9)		

For the ScanScope AT Turbo ER Precision Study, 80 slides were obtained and included

(n =80). The results are shown in Table 8 and Table 9.

**Table 8:** Inter-system precision contingency tables for ER distribution at two different percent positive thresholds in three ScanScope AT Turbo devices

Scanscope AT Turbo		1% cutoff		Scanscope AT Turbo					
				System 2		System 3		System 3	
		<1%	1-100%	<1%	1-100%	<1%	1-100%	<1%	1-100%
System 1	<1%	28	1	28	1				
	1-100%	4	47	4	47				
System 2	<1%					31	1		
	1-100%					1	47		
PA		93.75%		93.75%		97.5%			
95% CI		(86.0, 97.9)		(86.0, 97.9)		(91.3, 99.7)			

Scanscope AT Turbo		10% cutoff		Scanscope AT Turbo					
				System 2		System 3		System 3	
		0-10%	11-100%	0-10%	11-100%	0-10%	11-100%	0-10%	11-100%
System 1	0-10%	44	0	44	0				
	11-100%	1	35	1	35				
System 2	0-10%					45	1		
	11-100%					1	33		
PA		98.75%		98.75%		97.5%			
95% CI		(93.2, 99.9)		(93.2, 99.97)		(91.3, 99.7)			

**Table 9:** Intra-system precision contingency tables for ER distribution at two different percent positive thresholds for three scans from the same ScanScope AT Turbo device

Scanscope AT Turbo		1% cutoff		Scanscope AT Turbo					
				Run 2		Run 3		Run 3	
		<1%	1-100%	<1%	1-100%	<1%	1-100%	<1%	1-100%
Run 1	<1%	29	0	27	2				
	1-100%	1	50	2	49				
Run 2	<1%					27	2		
	1-100%					3	48		
PA		98.75%		95%		93.75%			
95% CI		(93.2, 99.7)		(87.7, 98.6)		(86.0, 97.9)			

Scanscope AT Turbo		10% cutoff		Scanscope AT Turbo					
				Run 2		Run 3		Run 3	
		0-10%	11-100%	0-10%	11-100%	0-10%	11-100%	0-10%	11-100%
Run 1	0-10%	45	0	45	0				
	11-100%	0	35	0	35				
Run 2	0-10%					45	0		
	11-100%					0	35		
PA		100%		100%		100%			
95% CI		(95.5, 100)		(95.5, 100)		(95.5, 100)			

For the Scanscope CS2 ER Precision Study, 40 slides were obtained, however 2 slides were removed for not having a malignant tumor yielding a sample size of n= 38. The

results are shown in Table 10 and Table 11.

**Table 10:** Inter-system precision contingency tables for ER distribution at two different percent positive thresholds in three ScanScope CS2 devices

Scanscope CS2		1% cutoff		Scanscope CS2					
				System 2		System 3		System 3	
		<1%	1-100%	<1%	1-100%	<1%	1-100%	<1%	1-100%
System 1	<1%	12	1	13	0				
	1-100%	0	25	0	25				
System 2	<1%					12	1		
	1-100%					0	25		
PA		97.50%		100%		97.50%			
95% CI		(86.2, 99.9)		(90.7, 100)		(86.2, 99.9)			

  

Scanscope CS2		10% cutoff		Scanscope CS2					
				System 2		System 3		System 3	
		0-10%	11-100%	0-10%	11-100%	0-10%	11-100%	0-10%	11-100%
System 1	0-10%	16	1	16	1				
	11-100%	0	21	0	21				
System 2	0-10%					15	0		
	11-100%					0	23		
PA		97.37%		97.37%		100%			
95% CI		(86.2, 99.9)		(90.7, 100)		(86.2, 99.9)			

**Table 11:** Intra-system precision contingency tables for ER distribution at two different percent positive thresholds for three scans from the same ScanScope CS2 device

Scanscope CS2		1% cutoff		Scanscope CS2					
				Run 2		Run 3		Run 3	
		<1%	1-100%	<1%	1-100%	<1%	1-100%	<1%	1-100%
Run 1	<1%	13	0	13	0				
	1-100%	0	25	0	25				
Run 2	<1%					13	0		
	1-100%					0	25		
PA		100%		100%		100%			
95% CI		(90.7, 100)		(90.7, 100)		(90.7, 100)			

  

Scanscope CS2		10% cutoff		Scanscope CS2					
				Run 2		Run 3		Run 3	
		0-10%	11-100%	0-10%	11-100%	0-10%	11-100%	0-10%	11-100%
Run 1	0-10%	16	0	16	0				
	11-100%	0	22	0	22				
Run 2	0-10%					16	0		
	11-100%					0	22		
PA		100%		100%		100%			
95% CI		(90.7, 100)		(90.7, 100)		(90.7, 100)			

For the ScanScope AT Turbo PR Precision Study, 40 slides were obtained and included (n =40). The results are shown in Table 12 and Table 13.

**Table 12:** Inter-system precision contingency tables for PR distribution at two different percent positive thresholds in three ScanScope AT Turbo devices

Scanscope AT Turbo		1% cutoff		Scanscope AT Turbo					
				System 2		System 3		System 3	
		<1%	1-100%	<1%	1-100%	<1%	1-100%	<1%	1-100%
System 1	<1%	12	0	12	0				
	1-100%	0	28	1	27				
System 2	<1%					12	1		
	1-100%					0	27		
PA		100%		97.5%		97.5%			
95% CI		(91.2, 100)		(86.8, 99.9)		(86.8, 99.9)			

Scanscope AT Turbo		10% cutoff		Scanscope AT Turbo					
				System 2		System 3		System 3	
		0-10%	11-100%	0-10%	11-100%	0-10%	11-100%	0-10%	11-100%
System 1	0-10%	16	0	16	0				
	11-100%	0	24	0	24				
System 2	0-10%					16	0		
	11-100%					0	24		
PA		100%		100%		100%			
95% CI		(91.2, 100)		(91.2, 100)		(91.2, 100)			

**Table 13:** Intra-system precision contingency tables for PR distribution at two different percent positive thresholds for three scans from the same ScanScope AT Turbo device

Scanscope AT Turbo		1% cutoff		Scanscope AT Turbo					
				Run 2		Run 3		Run 3	
		<1%	1-100%	<1%	1-100%	<1%	1-100%	<1%	1-100%
Run 1	<1%	12	0	12	0				
	1-100%	0	28	0	28				
Run 2	<1%					12	0		
	1-100%					0	27		
PA		100%		100%		100%			
95% CI		(91.2, 100)		(91.2, 100)		(91.2, 100)			

Scanscope AT Turbo		10% cutoff		Scanscope AT Turbo					
				Run 2		Run 3		Run 3	
		0-10%	11-100%	0-10%	11-100%	0-10%	11-100%	0-10%	11-100%
Run 1	0-10%	16	0	16	0				
	11-100%	0	24	0	24				
Run 2	0-10%					16	0		
	11-100%					0	24		
PA		100%		100%		100%			
95% CI		(91.2, 100)		(91.2, 100)		(91.2, 100)			

For the Scanscope CS2 PR Precision Study, 40 slides were obtained and included (n =40). The results are shown in Table 14 and Table 15.

**Table 14:** Inter-system precision contingency tables for PR distribution at two different percent positive thresholds in three ScanScope CS2 devices

Scanscope CS2		1% cutoff		Scanscope CS2					
				System 2		System 3		System 3	
		<1%	1-100%	<1%	1-100%	<1%	1-100%	<1%	1-100%
System 1	<1%	16	0	16	0				
	1-100%	0	24	0	24				
System 2	<1%					16	0		
	1-100%					0	24		
PA		100%		100%		100%			
95% CI		(91.2, 100)		(91.2, 100)		(91.2, 100)			

Scanscope CS2		10% cutoff		Scanscope CS2					
				System 2		System 3		System 3	
		0-10%	11-100%	0-10%	11-100%	0-10%	11-100%	0-10%	11-100%
System 1	0-10%	18	0	18	0				
	11-100%	0	22	0	22				
System 2	0-10%					18	0		
	11-100%					0	22		
PA		100%		100%		100%			
95% CI		(91.2, 100)		(91.2, 100)		(91.2, 100)			

**Table 15:** Intra-system precision contingency tables for PR distribution at two different percent positive thresholds for three scans from the same ScanScope CS2 device

Scanscope CS2		1% cutoff		Scanscope CS2					
				Run 2		Run 3		Run 3	
		<1%	1-100%	<1%	1-100%	<1%	1-100%	<1%	1-100%
Run 1	<1%	16	0	16	0				
	1-100%	0	24	0	24				
Run 2	<1%					16	0		
	1-100%					0	24		
PA		100%		100%		100%			
95% CI		(91.2, 100)		(91.2, 100)		(91.2, 100)			

Scanscope CS2		10% cutoff		Scanscope CS2					
				Run 2		Run 3		Run 3	
		0-10%	11-100%	0-10%	11-100%	0-10%	11-100%	0-10%	11-100%
Run 1	0-10%	18	0	18	0				
	11-100%	0	22	0	22				
Run 2	0-10%					18	0		
	11-100%					0	22		
PA		100%		100%		100%			
95% CI		(91.2, 100)		(91.2, 100)		(91.2, 100)			

*c. Linearity:*

Not applicable

*d. Carryover:*

Not applicable

*e. Interfering Substances:*

Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

None

**K. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**L. Conclusion:**

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