510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k062428

B. Purpose for Submission:
New application on approved system

C. Measurand:
p53 nuclear protein

D. Type of Test:
Computer-assisted image analyzer for p53 nuclear protein immunohistochemistry (qualitative immunocytochemistry).

E. Applicant:
TriPath Imaging, Inc.

F. Proprietary and Established Names:
Ventana Image Analysis System – p53 Application

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NQN- Microscope, Automated, Image Analysis, Immunohistochemistry, Operator Intervention, Nuclear Intensity and Percent Positivity	Class II	21CFR§ 864.1860 Immunohistochemistry reagents and kits	Pathology (88)

H. Intended Use:

1. Intended use(s):

   This antibody is intended for *in vitro* diagnostic (IVD) use.
   Ventana® Medical Systems' (Ventana) CONFIRM anti-p53 (DO-7) primary antibody is a mouse monoclonal antibody (IgG1, kappa) directed against human p53. The antibody is intended for laboratory use to qualitatively identify by light microscopy wild type and mutant p53 in sections of formalin fixed, paraffin embedded tissue on a Ventana automated slide stainer.

   The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician

2. Indication(s) for use:

   The ***Ventana Image Analysis System*** (VIAS™) is an adjunctive computer-assisted image analysis system functionally connected to an interactive microscope. It is intended for use as an aid to the pathologist in the detection, classification and counting of cells of interest

based on marker intensity, size and shape using appropriate controls to assure the validity of the VIAS scores.

In this application, the VIAS is intended to aid a qualified pathologist in the acquisition and measurement of images to quantify the percentage of positively stained nuclei in formalin-fixed, paraffin-embedded breast cancer tissue specimens immunohistochemically stained for the presence of p53 proteins using Ventana's reagents and nuclear hematoxylin. p53 over-expression is indicated for use as a marker of alterations of the p53 gene in breast tissue when used with in vitro diagnostic reagents marketed for these indications.

The VIAS 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 p53 receptor protein. 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 Ventana p53 assay to assure the validity of the VIAS-assisted p53 assessment.

3. Special conditions for use statement(s):
    This device is for prescription use only.
4. Special instrument requirements:
    The Ventana Image Analysis System – p53 Application requires the Ventana Image Analysis System (VIAS). The VIAS™ version 2.1 was cleared in 510(k) submission k053520. VIAS™ has since been upgraded to version 2.2 which is included in this submission. VIAS version 2.2 is a Software Minor Version update which includes minor enhancements or improvements to the VIAS. The minor software modifications did not result in new risks or changes to existing risks for the VIAS device. The document titled 3.0 VIAS Version 2.2 Software Documentation Index indicates which software documents are new or updated since the last submission.

I. **Device Description:**
The *VIAS* is an interactive histology imaging device that performs image processing using a microscope, digital color video camera, computer, and image analysis software to acquire and analyze user-selected images on p53 histology slides. As result of the quantitative analysis of these images the system presents the percent of p53 positive nuclei detected within the selected fields on a scale of 0% - 100%.

The *VIAS* consists of a single workstation with two main software applications for administration and slide processing. The workstation components include a microscope, motorized stage, digital color video camera, computer, monitor, keyboard, mouse, and barcode reader. The workstation is a table-top unit designed to be placed in the Pathologist office or lab space.

The device is intended to provide quantitative input to the Pathologist to supplement the qualitative interpretation of p53 slides. The Pathologist performs the usual manual read of the p53 slides to assess the p53 expression as score on a scale (0% to 100% positive stained cells) for the slide using the *VIAS* microscope. The Pathologist then has the opportunity to

select multiple fields of view using the **VIAS** microscope and computer for quantitative analysis. The **VIAS** device processes the user-selected color images to assess the p53 expression using a software algorithm that is the mathematical equivalent to the Pathologist's qualitative read.

The Pathologist makes the final call based on both the qualitative and quantitative information. It is recommended that in this application of the ***Ventana Image Analysis System*** the user follow the appropriate instructions in the Ventana p53 assay package insert. During the course of a p53 slide evaluation the Pathologist manually screens the slide using the interactive microscope of the ***Ventana Image Analysis System***. At any time during this screening process the Pathologist can acquire color images of fields of interest within tumor areas via the digital color camera mounted on top of the microscope. The selection of the tumor areas is the sole responsibility of the Pathologist. The Pathologist can refine his/her selection by marking specific tumor regions within acquired images with an interactive drawing tool. These color images are quantitatively evaluated by the ***Ventana Image Analysis System***.

The evaluation includes as a first step the separation of the two dye components DAB (brown) and hematoxylin (blue). The parameters for the dye characterization are stored in a slide type storage structure containing assay specific parameters to process p53 slides. The slide type for the p53 assay contains the name of the assay (p53), Counterstain (Hematoxylin), Marker Stain (DAB), Marker Expression Localization (Nucleus) and the magnification of the objective used for quantitative analysis (20x). The p53 slide type is optimized for Ventana's p53 assay using Ventana's DAB copper chromogen and nuclear hematoxylin.

The calculation of the p53 percent positive score is based on the number of positive and negative nuclei detected in the brown (DAB) and blue (hematoxylin) images. The nuclei of positive tumor cells can be seen in both the blue and brown images. Nuclei of negative tumor cells – in the ideal case – have no brown nuclear image component. However, due to cytoplasmic stain this is only very rarely the case. As the cytoplasm of a cell covers its nucleus, cytoplasmic foreground stain makes a negative nucleus look positive.

Establishing the System Score Formula
For the purpose of calculating the percent positive cells the **VIAS** system uses a score formula, which automatically corrects for potential cytoplasmic foreground stain. This formula determines the percentage of nuclei that exhibit specific positive staining. The positive/negative threshold calculation contained in the formula is a function of the noise level indicated by the measured mean intensity of DAB in the cytoplasm. The minimum value of the threshold is 0.02, establishing a reasonable lower bound for the cytoplasmic staining noise level. This threshold value increases as the cytoplasmic staining noise level rises above the minimum value, allowing the system to look for the appropriate level of specific staining in the nucleus, relative to the staining detected in the cytoplasm. The final percent positive number is calculated by the **VIAS** system as a ratio of all detected nuclei determined as positive and accumulated over all fields selected by the pathologist for a

particular slide and the total number of detected nuclei (negative and positive) within these fields multiplied by 100%.

Interactive Region Correction

To avoid an inflated denominator due to normal cell nuclei included in the count of negative nuclei in this ratio it is important to segment out normal nuclei. *VIAS* provides two tools which are designed to do this. When an image is acquired, *VIAS* by default refines the region of interest by excluding most of the stroma cells (see *Operator's Manual, Chapter 4, Defining regions on the field*). This region of interest is presented as a suggestion to the operator who can either accept it or further refine it with the drawing tool (see *Operator's Manual, Chapter 4, Defining regions on the field*). The drawing tool enables the interactive addition or subtraction of objects or regions to the region of interest within the displayed image. The region of interest is the part of the stored image which will be quantitatively evaluated by *VIAS*.

Each laboratory can set the threshold to the normal range preferred by their Pathologist for the p53 assay. Typical cut-off values are 1%, 5%, and 10% positive tumor cells [*1)* Hamilton *et al.; 2)* Yamashita *et al.; 3)* Bull *et al.; 4)* Stenmark-Askmalm *et al.; 5)* MacGrogan *et al.; 6)* Sirvent *et al.*

J. Substantial Equivalence Information:

Predicate	k053520 - Ventana Image Analysis System - Ki-67
Describe the item being compared	
The Ventana Image Analysis System (VIAS™) is the same system in this submission that has been cleared for the previous indications ER/PR (k050012), HER-2/neu (k051282) and most recently the predicate device Ki-67 (k053520). p53 is an antibody that when stained indicates over-expression of a protein that is associated with cellular abnormality. The VIAS, with its previously cleared uses, is indicated for use as an aid in the management and prognosis of breast cancer when used with in vitro diagnostic reagents for these indications.	

Similarities		
Item	Device	Predicate
Hardware and Software	VIAS System	VIAS System
Specimen	Formalin-fixed paraffin-embedded breast cancer specimens stained by immunohistochemical (IHC) technique	Formalin-fixed paraffin-embedded breast cancer specimens stained by immunohistochemical (IHC) technique
Localization of IHC positive stain	Nuclear	nuclear
Interpretation	By the pathologist. The VIAS aids the pathologist in the interpretation of the specimen.	By the pathologist. The VIAS aids the pathologist in the interpretation of the specimen.

Differences		
Item	Device	Predicate
IHC Antigen Detected	P53	Ki-67

K. Standard/Guidance Document Referenced (if applicable):

STANDARDS
Title and Reference Number
Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline - Second Edition (GP19-A2)
Standard for Software Verification and Validation (1012:1998)
Medical devices - Risk management - Part 1: Application of risk analysis (14971-1)

Other Standards

GUIDANCE			
Document Title	**Office**	**Division**	**Web Page**
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff	**ODE**		**http://www.fda.gov/cdrh/ode/guidance/337.html**
Guidance for Off-the-Shelf Software Use in Medical Devices; Final	**ODE**		**http://www.fda.gov/cdrh/ode/guidance/585.html**
Indications for Use Statement	**ODE**		**http://www.fda.gov/cdrh/ode/indicuse.html**
In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions	**OCER**		**http://www.fda.gov/cdrh/manual/ivdmanul.html**

L. Test Principle:

The device methodology is well established for nuclear staining and previously cleared for Ki-67 on the VIAS (k053520).

The VIAS is an interactive histology imaging device that performs image processing using a microscope, digital color video camera, computer, and image analysis software to acquire and analyze user-selected images on p53 histology slides. As a result of the quantitative analysis of these images the system presents the percent of p53 positive nuclei detected within the selected fields on a scale of 0% - 100%.

The VIAS consists of a single workstation with two main software applications for administration and slide processing. The workstation components include a microscope, motorized stage, digital color video camera, computer, monitor, keyboard, mouse, and barcode reader. The workstation is a table-top unit designed to be placed in the Pathologist office or lab space.

M. Performance Characteristics (if/when applicable):
1. Analytical performance:
   a. *Precision/Reproducibility:*
      Instrument Precision

To determine the precision of the *Ventana Image Analysis System* between-run reproducibility studies were conducted. To evaluate the between run precision on each system the selected field of view for each of the nine slides of a study set was measured once before repeating the same sequence another four (4) times on the same system. This resulted in five (5) instrument score values for each field of view per slide, where between the measurements the slide was removed and placed back on the microscope stage. After finishing with the first system (Table 1), the study was repeated on system 2 (Table 2) and 3 (Table 3).

The study set consisted of nine (9) slides with formalin-fixed, paraffin-embedded tissue specimens immunohistochemically stained for p53 protein expression using Ventana's p53 assay labeled with Ventana's iVIEW™ DAB chromogen and Ventana's nuclear hematoxylin. The study slides were selected with mean per cent positive p53 tumor cells of around 0, 1, 5, 10, 20, 30, 50, 70 and 90 per cent. In this study one (1) field of view for each of the nine (9) p53 slides was measured five (5) times on three (3) different *Ventana Image Analysis Systems*. The three systems were calibrated by carefully adjusting the microscopes (see *Microscope User's Guide*) and setting up the slide types for p53 in an identical fashion (see *Application Addendum – p53* in the *Application Specific Information* section). To achieve best image quality on all three systems the acquisition of the Black and White Reference Images is controlled during the image acquisition process by each system (see *VIAS Operator's Manual: Acquiring reference images* in *Chapter 4: Screening a slide* for more information).

The study results are presented in Table 1 through Table 3. For each slide, the mean, the standard deviation (SD), and the coefficient of variation (CV) of the instrument score readings were calculated. The number (n) of repeats per study is listed in the header of each table.

Table 1: Results of the Between Run Precision Study - System

p53 (n = 5)							
Slide #	Mean Score	SD Score	%CV [%]	Slide #	Mean Score	SD Score	%CV [%]
1	0.0	0.00	N/A	2	1.0	0.00	0.00
3	6.2	0.45	7.21	4	11.6	0.55	4.72
5	20.8	0.45	2.15	6	30.8	1.64	5.33
7	50.6	2.97	5.86	8	69.8	1.92	2.76
9	92.0	0.00	0.00				

Table 2: Results of the Between Run Precision Study - System 2

p53 (n = 5)							
Slide #	Mean Score	SD Score	%CV [%]	Slide #	Mean Score	SD Score	%CV [%]
1	0.0	0.00	N/A	2	1.0	0.00	0.00

p53 (n = 5)							
Slide #	Mean Score	SD Score	%CV [%]	Slide #	Mean Score	SD Score	%CV [%]
3	5.8	0.45	7.71	4	14.0	0.71	5.05
5	21.0	0.71	3.37	6	32.0	1.23	3.83
7	50.8	1.10	2.16	8	70.6	0.55	0.78
9	91.0	0.00	0.00				

Table 3: Results of the Between Run Precision Study - System 3

53 (n = 5)							
Slide #	Mean Score	SD Score	%CV [%]	Slide #	Mean Score	SD Score	%CV [%]
1	0.0	0.00	N/A	2	1.0	0.00	0.00
3	5.6	0.55	9.78	4	13.8	0.45	3.24
5	22.2	2.05	9.23	6	31.4	2.19	6.98
7	56.2	1.92	3.42	8	70.8	0.45	0.63
9	91.0	0.00	0.00				

Table 4 shows the summary results of the Inter-System Precision study based on systems 1, 2 and 3. The columns labeled with M Mean present the mean values of the 3 mean instrument score values of system 1, 2, and 3. SD* lists standard deviation values. The CV* columns present the corresponding coefficients of variation. Both the SD* and CV* were calculated utilizing a propagation of variance formula which incorporates both intra- and inter-system variance calculations.

Table 4: Summary results of the (Between Run) Inter-System Reproducibility Study – Systems 1, 2, 3

p53 (n = 5)							
Slide #	Mean Score	SD Score	%CV [%]	Slide #	Mean Score	SD Score	%CV [%]
1	0.0	0.00	N/A	2	1.0	0.00	0.00
3	5.9	0.57	9.81	4	13.1	1.49	11.06
5	21.3	1.49	6.81	6	31.4	1.83	5.85
7	52.5	3.83	7.31	8	70.4	1.30	1.85
9	91.3	0.58	0.63				

Reproducibility results may vary depending on the composition of the field of view chosen for analysis.

b. *Linearity/assay reportable range:*
Linearity is not applicable. The assay reportable range is 0% to 100% positive tumor cells.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The VIAS does not require use of external calibrators or controls; therefore, stability, traceability, value assignment, etc. do not apply. Ventana Medical Systems, Inc., the manufacturer of the Class I IHC reagents used in this application, is responsible for good manufacturing practices that assure the stability of the reagents.

For external controls, refer to the Ventana® CONFIRM™ anti-p53 Primary Antibody Package Insert. The package insert describes the positive and negative controls to be assembled by each laboratory for use to control their assay. They are not traceable to a higher standard. Each laboratory assigns their own values to control materials used.

d. *Detection limit:*
The Ventana Confirm™ anti-p53 (DO-7) Primary Antibody indicated that, "Sensitivity is dependent upon the preservation of the antigen. Any improper tissue handling during the fixation, sectioning, embedding or storage which alters antigenicity weakens the p53 detection by Confirm™ anti-p53 (DO-7) and may generate false negative results".

e. *Analytical specificity:*
The Ventana Confirm™ anti-p53 (DO-7) Primary Antibody indicated that, "Specificity of CONFIRM anti-p53 (DO-7) was determined by a study that showed appropriate staining of normal and neoplastic tissues. For each normal tissue type, multiple cases were stained from different sources on the BenchMark automated slide stainer. For normal tissues, results are as follows:

Tissue type	Number	Negative	Positive
Breast	9	8	1*
Thyroid	9	6	3(mild staining intensity)
Spleen/Tonsil	9	9	0
Uterus	9	2	7*
Prostate	9	7	2*
Testis	9	1	8*
Ovary	9	9	0
Pancreas	9	5	4*
Lung	9	8	1*
Liver	9	9	0
Kidney	9	6	3*
Heart	9	9	0
Intestine	9	6	3
Brain	9	9	0
Skin	9	4	5*
Adrenal	9	9	0

* Focal staining

For neoplastic tissues 2 out of 2 cases stained positive for the following:
- Liver cancer
- Stomach cancer
- Pancreatic cancer
- Undifferentiated cancer

- Melanoma
- Colon
- Carcinoids
- Lymphona

Negative staining in 2 out of 2 cases of the following neoplastic tissues:
- Kidney
- Lung
- Breast
- Prostate

Moderate positive staining occurred in 2 out of 2 cases for the following neoplastic tissues: ovary, thyroid and sarcoma.

f. *Assay cut-off:*

Each laboratory can set the threshold for positivity preferred by their pathologist for the p53 assay. Typical cutoff values used are 1%, 5%, and 10% positive tumor cells. The pathologist makes the final call based on both qualitative and quantitative information seen in the tissue section.

2. Comparison studies:

a. *Method comparison with predicate device:*

Study Design: The predicate device for the comparison of the automated image analysis was the manual method performed by the pathologist on the same set of 204 formalin-fixed, paraffin-embedded breast tissue specimens obtained from an outside source. They were immunohistochemically stained using Ventana's p53 reagents (3 staining lots) labeled with Ventana's DAB copper chromogen and nuclear hematoxylin. The slides were selected in such a way that approximately one third of the cases were p53 negative, approximately one third were in the range of 1% - 25% p53 tumor cell positivity, and approximately one third of the cases showed more than 25% p53 positive tumor cells.

As preparation for the comparison study one board-certified pathologist screened each slide of the study sample using the microscope of one ***Ventana Image Analysis System*** and selected and stored between three (3) and six (6) images (along with their corresponding location coordinates) of diagnostically significant fields. For each slide the pathologist also noted down the manual score value as result of the manual scoring of the selected fields. During this process 4 slides were excluded from the initial sample by the pathologist for various reasons (e.g. bad fixation, not enough tumor). The images and the coordinates of their related slide locations were then copied to the databases of three (3) different ***Ventana Image Analysis Systems***.

During the comparison study three (3) different board-certified pathologists performed a manual read in a blinded manner of each slide of the study sample by having the preselected fields of interest automatically relocated underneath the microscope of one ***Ventana Image Analysis System***. Each pathologist was using the microscope of a different system (e.g. pathologist 1 used system 1, pathologist 2 used system 2, pathologist 3 used system 3). Each system was validated and checked for conformity prior to use in this study. For this portion of the trial, the imaging system software was switched to a mode where it did not display any quantitative results.

Each relocated field was recaptured and stored for the subsequent quantitative evaluation by the system. The pathologists based their manual reads exclusively on the pre-selected fields of view which had been chosen by the independent pathologist prior to the reading of the study sample set. For the purpose of the study the pathologists were not screening the entire slide. At the end of each slide assessment the pathologist recorded his/her manual score in a table provided for the study.

Based on the recaptured images the system automatically computed the % positivity scores for each slide. The slide score results were later retrieved from the system and used in the subsequent data analysis. Since different laboratories are known to use different cutoff thresholds, Table 5 shows the concordance range for the manual scores of the three study pathologists with the corresponding system scores (column two in table 5), the concordance range between the system scores (column three in table 5) and the concordance range between the manual scores of the three (3) study pathologists (column four in table 5). The concordance ranges are given for the three example cutoff thresholds of pos $\geq$ 1%, pos $\geq$ 5%, and pos $\geq$ 10% positive stained tumor cells.

Table 5: Concordance ranges for p53 staining

Cutoff Threshold	Pathologist – System Concordance 1 for Three Pathologist – System pairs	Pathologist – Pathologist Concordance 2 between Three Pathologists	System – System Concordance 3 for three VIAS systems
1%	92.0 – 94.5%	88.5 – 98.5%	96.5 – 98.0%
5%	87.0 – 98.0%	84.5 – 87.5%	99.5 – 100%
10%	86.0 – 96.5%	85.0 – 93.0%	99.0 – 99.5%

[1] Range of concordances seen between the three (3) system – pathologist pairs
[2] Range of concordances seen between the three (3) different pathologists (manual call)
[3] Range of concordances seen between the three (3) different corresponding system calls

Conclusion: Expected Results
The ***Ventana Image Analysis System*** is designed to provide quantitative input to the Pathologist to supplement the qualitative interpretation of p53 slides. The selection of diagnostically meaningful fields of view for the quantification is the responsibility of the Pathologist.

The high concordance values between System and Pathologist (86.0 – 98.0% for cutoff values 1%, 5% and 10%) show in comparison to similarly high concordance values for the Pathologist to Pathologist read (84.5 – 98.5% for the same cutoff values) and the corresponding System to System read (96.5 – 100.0% for the same cutoff values) that the likelihood of the ***Ventana Image Analysis System*** to produce a consistent score on a given slide is as likely as the Pathologists are to agree with each other. These results are based on each Pathologist and each system reading the same preselected fields of view.

  b. Matrix comparison:
   Not applicable since the only matrix is formalin-fixed paraffin-embedded tissue
   section stained slide.
 3. <u>Clinical studies</u>:
  a. Clinical Sensitivity:
   No clinical studies were performed. The clinical sensitivity of the test result is
   dependent on the analytical performance of the Ventana Confirm™ anti-p53 (DO-7)
   Primary Antibody kit.
  b. Clinical specificity:
   No clinical studies were performed. The clinical sensitivity of the test result is
   dependent on the analytical performance of the Ventana Confirm™ anti-p53 (DO-7)
   Primary Antibody kit.
  c. Other clinical supportive data (when a. and b. are not applicable):
   Not applicable.
 4. <u>Clinical cut-off</u>**:**
  Same as assay cut-off.
 5. <u>Expected values/Reference range</u>:
  The Confirm™ anti-p53 (DO-7) Primary Antibody kit is sold by Ventana as a Class I
  immunohistochemistry (IHC) reagent. No clinical claims are appropriate for a Class I
  IHC reagent.

N. Instrument Name:
 Ventana Image Analysis System (VIAS)

O. System Descriptions:
 1. <u>Modes of Operation</u>:
  Interactive with user
 2. <u>Software</u>:
  The operating system used in the VIAS is Microsoft Windows XP integrated with a
  proprietary user interface. The VIAS system interfaces with Microsoft SQL Server. The
  VIAS does not interface with a laboratory information system. It is a stand-alone system
  and does not communicate with other systems in this application.
  FDA has reviewed applicants Hazard Analysis and software development processes for
  this line of product types:
  Yes ___X_____ or No _____
  Mr. Joseph Jorgens III has reviewed the original software submission and the updated
  version 2.2 and found it to be acceptable for a moderate hazard level.
 3. <u>Specimen Identification</u>:
  Specimen identification is by barcode applied to the slides manually.
 4. <u>Specimen Sampling and Handling</u>:
  The microscope slides to be examined are loaded onto the microscope stage manually
  one-at-a-time.
 5. <u>Calibration</u>:
  The VIAS software calculates an internal control. As the cytoplasm of a cell covers its
  nucleus, cytoplasmic foreground stain makes a negative nucleus look positive. For the
  purpose of calculating the output (percent positive cells) the VIAS system uses a score
  formula that automatically corrects for potential cytoplasmic foreground stain. This
  formula determines the percentage of nuclei that exhibit specific positive staining. The

positive/negative threshold calculation contained in the formula is a function of the noise level indicated by the measured mean intensity of DAB in cell's cytoplasm. The minimum value of the threshold is 0.02, establishing a reasonable lower bound for the cytoplasmic staining noise level. This threshold value increases as the cytoplasmic staining noise level rises above the minimum value, allowing the system to look for the appropriate level of specific staining in the nucleus, relative to the staining detected in the cytoplasm.

6. Quality Control:
   The quality of the result depends on the laboratory following the quality control instructions recommended in the labeling of the accessory immunohistochemistry (IHC) assay kit used with the VIAS.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The Performance Characteristics Section above:
None

Q. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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