



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP 29 2006

TriPath Imaging, Inc.  
c/o Bryan J. Tucker, PhD  
Vice President, Clinical and Regulatory Affairs  
4025 Stirrup Creek Drive  
Suite 400  
Durham, NC 27703

Re: k062428

Trade/Device Name: Ventana Image Analysis System (VIAS™) – p53  
Regulation Number: 21 CFR 864.1860  
Regulation Name: Microscope Automated Image Analyzers, Immunohistochemistry  
Regulatory Class: Class II  
Product Code: NQN  
Dated: August 17, 2006  
Received: August 22, 2006

Dear Dr. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.  
Director

Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

K062428

Device Name: Ventana Image Analysis System – p53

Indications 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.

Prescription Use   X  

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

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Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K062428