APR 1 1 2006

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

Re: k053520
    Trade/Device Name: Ventana Image Analysis System – Ki-67
    Regulation Number: 21 CFR 864.1860
    Regulation Name: Immunohistochemistry reagents and kits
    Regulatory Class: Class II
    Product Code: NQN
    Dated: December 16, 2005
    Received: December 20, 2005

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.

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 (301) 443-6597 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): K053520

Device Name: Ventana Image Analysis System – Ki-67

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 paraffin embedded breast cancer tissue specimens immunohistochemically stained for the presence of Ki-67 proteins using Ventana's reagents and nuclear hematoxylin. It is indicated for use in assessing the proliferative activity of normal and neoplastic 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 Ki-67 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 Ki-67 kit to assure the validity of the VIAS-assisted Ki-67 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)

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

Maura Chan
Division Sign-Off

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Device Evaluation and Safety**   Page 1 of ___1__

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