DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2005

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

Re: k051282
Trade/Device Name: Ventana Image Analysis System – Her2/neu
Regulation Number: 21 CFR 864.1860
Regulation Name: Immunohistochemistry reagents and kits
Regulatory Class: Class II
Product Code: NOT
Dated: May 16, 2005
Received: May 17, 2005

Dear Mr. 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 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety 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., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051282

Device Name: Ventana Image Analysis System – Her2/neu

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 for the semi-quantitative detection of c-erbB-2 (HER-2/neu) in formalin-fixed, paraffin embedded normal and neoplastic tissue specimens immunohistochemically stained for the presence of HER-2/neu proteins using Ventana's HER-2/neu reagents as well as Ventana's DAB copper chromogen and nuclear hematoxylin.

This particular application is an accessory to the Ventana PATHWAY™ Her2 (clone CB11) (Ventana Medical Systems, Inc., Tucson, Arizona) and the Ventana PATHWAY™ Her2 is indicated as an aid in the assessment of breast cancer patients for whom Herceptin® treatment is considered.

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 HER2 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 PATHWAY™ Her2 to assure the validity of the VIAS-assisted HER2 score.

Note: All of the patients in the Herceptin® clinical trials were selected using a clinical trial assay. None of the patients in those trials were selected using PATHWAY™ Her2. The PATHWAY™ Her2 was compared to the DAKO HercepTest™ on an independent sample and found to provide acceptably concordant results. The actual correlation of PATHWAY™ Her2 to clinical outcome has not been established.

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 Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051282