

3/31/99

K990311



## Premarket Notification [510(k)] Summary

**Company:** ABX Diagnostics, Inc.  
34 Bunsen Drive  
Irvine, CA 92618  
Phone: (949) 453-0500  
FAX: (949) 453-0600  
Contact Person: Franck Brouzes  
Date Prepared: January 18, 1999

**Trade Name:** VEGA RETIC Automated Hematology Analyzer

**Common Name:** Automated cell counter and  
Automated differential cell counter

**Classification Name:** Automated cell counter (864.5200) and  
Automated differential cell counter (864.5220)

### Substantial Equivalence:

The VEGA RETIC Automated Hematology Analyzer is substantially equivalent to the following devices:

- VEGA Hematology Analyzer (K962633, cleared to market November 4, 1996).
- SYSMEX R-3000 Automated Reticulocyte Analyzer (K912494, cleared for market September 10, 1991).

### Description:

The VEGA RETIC Automated Hematology Analyzer is a benchtop, clinical laboratory instrument which analyzes *in-vitro* samples of whole blood to provide complete blood count, leucocyte differential count and reticulocyte count using principles of cytochemistry, focused flow impedance, light scattering, and fluorescence. The instrument is microprocessor driven.



### **Indications For Use:**

The **VEGA RETIC Automated Hematology Analyzer** is an automated hematology analyzer providing complete blood count, differential leucocyte count as well as reticulocyte count for *in vitro* diagnostic use in clinical laboratories. The **VEGA RETIC Automated Hematology Analyzer** provides appropriate flags and alarms to assist users in final checking and identification of abnormal cell populations.

### **Comparison to Predicate Devices:**

**VEGA RETIC Automated Hematology Analyzer** is essentially identical to the VEGA Hematology Analyzer with respect to the indications for use for the hematological parameters for complete blood count and differential leucocyte count. The reagents and controls and the technological characteristics (cytochemistry, focused flow impedance and light scattering) are the same.

**VEGA RETIC Automated Hematology Analyzer** is similar to the SYSMEX R-3000 with respect to the indications for use for the reticulocyte count. The reagents and controls are similar. The technological characteristics are similar: both systems use a fluorescent dye and argon optical laser bench to measure forward scattered light and forward fluorescence.

### **Discussion of Performance Data:**

The determination of substantial equivalence is based on an assessment of clinical performance data comparing results from 200 human whole blood samples processed in the **VEGA RETIC Automated Hematology Analyzer** and in the SYSMEX R-3000 with respect to correlation between the two procedures.

In addition the within-run, between run, and between-day precision of the **VEGA RETIC Automated Hematology Analyzer** was evaluate using three commercially available control specimens having low, normal and high reticulocyte counts. These results were compared to publicly available data for the SYSMEX R-3000.

The following additional performance assessments were made: assay linearity, sample stability over time at ambient and low temperatures, and the carry-over effect from a high reticulocyte count sample to a low reticulocyte count sample.



### **Conclusions:**

Performance data comparing the **VEGA RETIC Automated Hematology Analyzer** and the **SYSMEX R-3000** demonstrated that the absolute/proportional reticulocyte counts and absolute erythrocyte counts generated on clinical specimens tested with each procedure are highly correlated. Additionally performance data demonstrated that the within-run, between run, and between-day precision characteristics of the two procedure are very similar. The **VEGA RETIC Automated Hematology Analyzer** provides linear absolute/proportional reticulocyte count data over a broad range of values. Performance data indicate that very little sample carry-over occurs and that samples stored up to 48 hours at 4°C provide reliable estimates of absolute/proportional reticulocyte counts and samples stored up to 72 hours at ambient or 4°C provide reliable estimates of erythrocyte counts.

Prepared By: Patricia Amtower  
Consultant, ProMedica International



MAR 31 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Franck Brouzes  
Vice President  
ABX Diagnostics, Inc.  
34 Bunsen Drive  
Irvine, California 92618

Re: K990311  
Trade Name: ABX™ PENTRA 120 RETIC Automated Hematology Analyzer  
Regulatory Class: II  
Product Code: GKZ  
Dated: January 28, 1999  
Received: February 1, 1999

Dear Mr. Brouzes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895.

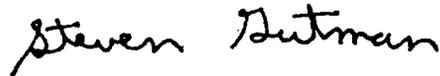
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D, M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K990311

Device Name: VEGA RETIC Automated Hematology Analyzer

Indications For Use:

The VEGA RETIC Automated Hematology Analyzer is an automated hematology analyzer providing complete blood count (CBC), differential leucocyte count (DIFF) as well as reticulocyte count for *in vitro* diagnostic use in clinical laboratories. The VEGA RETIC Automated Hematology Analyzer provides appropriate flags and alarms to assist users in final checking and identification of abnormal cell populations.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

  
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(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K990311