

AUG 11 1999

K991839



DIAGNOSTICS

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: May 21, 1999

Trade Name: ABX™ PENTRA 120 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 ABX PENTRA 120 RETIC Automated Hematology Analyzer is substantially equivalent to the ABX PENTRA 120 RETIC Automated Hematology Analyzer (K990311, cleared to market March 31, 1999) and to the Sysmex™ IRF clinical parameter (K971736, cleared to market August 26, 1997).

Description:

The ABX PENTRA 120 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 **ABX PENTRA 120 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 **ABX PENTRA 120 RETIC Automated Hematology Analyzer** provides appropriate flags and alarms to assist users in final checking and identification of abnormal cell populations.

The clinical use of the reticulocyte count, specifically the immature reticulocyte fraction (IRF) is to monitor erythropoietic activity in patients.

Comparison to Predicate Devices:

ABX PENTRA 120 RETIC Automated Hematology Analyzer is identical to the **ABX PENTRA 120 RETIC Hematology Analyzer** with respect to the reagents and controls, measuring principles, principles of operation, hardware, and software. The **ABX PENTRA 120 RETIC Automated Hematology Analyzer** labeling was modified to include an additional parameter for reticulocyte counts: the IRF parameter. With respect to this parameter, the IRF parameter is substantially equivalent to the Sysmex R-Series IRF parameter. ABX Diagnostics defines the IRF parameter as the sum of the medium and high RNA content reticulocytes (as %). Sysmex Corporation defines the IRF parameter as the sum of the middle fluorescence ratio and the high fluorescence ratio.

Discussion of Performance Data:

The determination of substantial equivalence was based on an assessment of clinical performance data from published studies and from a clinical study using whole blood samples from 100 patients with normal reticulocyte counts and 103 patients with abnormal counts. In the clinical study, samples were processed in the **ABX PENTRA 120 RETIC Automated Hematology Analyzer** and the **SYSMEX R-3000 analyzer**. Clinical data support substantial equivalence for the IRF parameter. Additional studies were conducted to assess the precision and accuracy of the **ABX PENTRA 120 RETIC Automated Hematology Analyzer**.



Conclusions:

All studies confirmed that the IRF clinical parameter of the **ABX PENTRA 120 RETIC Automated Hematology Analyzer** is substantially equivalent to the Sysmex IRF clinical parameter.

Prepared By: Patricia Amtower
Consultant, ProMedica International



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 11 1999

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

Re: K991839
Trade Name: ABX™ PENTRA 120 RETIC Automated Hematology Analyzer
Regulatory Class: III
Product Code: GKZ
Dated: May 27, 1999
Received: May 28, 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.

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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 with a large initial 'S'.

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): K991839

Device Name: **ABX™ PENTRA 120 RETIC Automated Hematology Analyzer**

Indications For Use:

The **ABX PENTRA 120 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 **ABX PENTRA 120 RETIC Automated Hematology Analyzer** provides appropriate flags and alarms to assist users in final checking and identification of abnormal cell populations.

The clinical use of the reticulocyte count, specifically the immature reticulocyte fraction (IRF), is to monitor erythropoietic activity in patients.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991839

(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 _____