

K992511



DIAGNOSTICS

OCT 15 1999

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 15, 1999

Trade Name: ABX PENTRA 60™ 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 60™ Hematology Analyzer is substantially equivalent to the VEGA Hematology Analyzer (K962633, cleared to market November 4, 1996).

Description:

The ABX PENTRA 60™ Hematology Analyzer is a benchtop, clinical laboratory instrument which analyzes *in-vitro* samples of whole blood to provide complete blood count and leucocyte differential count using principles of cytochemistry, focused flow impedance and light transmission using a halogen light source. The instrument is microprocessor driven.

Indications For Use:

The ABX PENTRA 60™ Hematology Analyzer is a fully automated (microprocessor controlled) hematology analyzer used for the *in vitro* diagnostic testing of whole blood specimens.

The ABX PENTRA 60™ is able to operate either in complete blood count (CBC) mode or in CBC + 5 differential leucocyte count (5DIFF) mode.



Comparison to Predicate Devices:

The **ABX PENTRA 60™ Hematology Analyzer** is substantially equivalent to the already cleared device with respect to the indications for use, the hematological parameters for complete blood count and differential leucocyte count, and the principles of operation. It is different with respect to those modifications in hardware (mechanical and pneumatic) necessary to downsize the instrument, the added feature of pre-heated reagent block chambers, reduced specimen volume using a multi-distribution sampling system (MDSS), and slight changes in the reagents and the dilution ratios. The overall effect of these modifications on the safety and efficacy of the device have been evaluated in a clinical study. Software changes have been made to address the modifications and the new software has been validated.

Discussion of Performance Data:

The determination of substantial equivalence is based on an assessment on performance data on various hematological indices using human blood samples processed in the **ABX PENTRA 60™ Hematology Analyzer** and in the VEGA Hematology Analyzer. The human blood samples included 105 clinical specimens from patients having a normal complete blood count and 104 from patients having at least one parameter outside the normal range. Clinical samples were also used to evaluate sample stability.

Assay linearity/sensitivity and carry-over were evaluated using commercially available low range and high (full) range specimens. Within-run, between-run, and between-day precision were evaluated using three commercially available control specimens having leukocytes, erythrocytes, platelets, and hemoglobin the low, normal and high range.

Conclusions:

Performance data on various hematological parameters comparing the **ABX PENTRA 60™ Hematology Analyzer** and the VEGA Hematology Analyzer, assay linearity/sensitivity and carry-over studies and within-run, between run, and between-day precision studies indicate that the **ABX PENTRA 60™** is substantially equivalent to the predicate device.

Prepared By: Patricia Amtower
Consultant, ProMedica International



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 15 1999

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

Re: K992511
Trade Name: ABX PENTRA 60™ Hematology Analyzer
Regulatory Class: II
Product Code: GKZ
Dated: July 23, 1999
Received: July 27, 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.

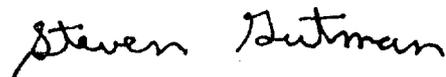
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,



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

