FEB 2 8 2002

K014203

SECTION B Premarket Notification [510(k)] Summary

Company: ABX Diagnostics, Inc.
34 Bunsen Drive
Irvine, CA 92618
Phone: (949) 453-0500 FAX: (949) 453-0600
Date Prepared: December 7, 2001

Contact Person: Tom M. Phillips

Date of Preparation: December 19, 2001

Trade/Proprietary Name: **ABX MICROS 60** Hematology Analyzer

Common or Usual Name: Automated cell counter and
Automated differential cell counter

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

Product Code: GKZ (Hematology Analyzer)

Substantial Equivalence: The **ABX MICROS 60** is substantially equivalent to the **BAKER SYSTEM 9110^{+} PLUS** Hematology Analyzer

Description: The **ABX MICROS 60** Hematology Analyzer is a bench top clinical laboratory instrument which analyzes *in vitro* samples of whole blood to provide complete blood count data using principles of cytochemistry, focused flow impedance, and light transmission technology. The system is equipped with automatic calibration; Automated smart cards based for: calibration, QC with 93 multiple range files and memory with 60 erasable results.

Indication for Use: The **ABX MICROS 60** Hematology Analyzer is a fully automated (microprocessor controlled) hematology analyzer used for the *in vitro* diagnostic testing of whole blood specimens or blood cell concentrates. It operates in complete blood count (CBC) mode.

Comparison to the Predicate Device:

The **ABX MICROS 60** Hematology Analyzer is equivalent to the **BAKER SYSTEM 9110^{+} PLUS** Hematology Analyzer; both instruments are fully automated hematology analyzers using whole blood to measure WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, and MPV. The **ABX MICROS 60** also measures differential

counts whereas the **BAKER SYSTEM 9110$^+$ PLUS** does not.

Discussion of Performance Data:

Data provided in the 510(k) application demonstrate that within-run, between-run, and between-day precision for the **ABX MICROS 60** is acceptable, with the highest CV (3.0%) being obtained for the high level control tested 10 times in succession on a single day, (B) the assay is quite linear from 250 to 5000 x $10^3/\mu L$, (C) results from the **ABX MICROS 60** assay are highly correlated with those derived from the **Baker System 9110$^+$ PLUS**, although the values tend to be somewhat lower, and (D) there is no carry-over when samples having low platelet counts are assayed after those with substantially higher counts.

Conclusion:

The **ABX MICROS 60** Hematology Analyzer provides reliable data when used to quantitate the number of platelets in preparations having relatively high concentrations of this analyte (250 – 5000 $10^3/\mu L$ range).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 8 2002

Mr. Tom M. Phillips
Manager of Regulatory Affairs
ABX Diagnostics, Inc.
34 Bunsen Drive
Irvine, CA 92618

Re: k014203
Trade/Device Name: ABX Micros 60 Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: December 19, 2001
Received: December 21, 2001

Dear Mr. Phillips:

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 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

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): K014203

Device Name: **ABX MICROS 60** Hematology Analyzer

Indications For Use:

The **ABX MICROS 60** Hematology Analyzer is a fully automated (microprocessor controlled) hematology analyzer used for the ***in vitro*** diagnostic testing of whole blood specimens or blood cell concentrates. It operates in complete blood count (CBC) mode.

(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 _____

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K014203