



APR 08 2003

Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K030799

Company: ABX Diagnostics
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Contact Person: Tim Lawton (tlawton@fr.abx.fr)

Date Prepared: 07 March, 2003

Device Name:

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

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

Device Class: Class II : Special Controls Guidance Document

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

Product Code: GKZ

Substantial Equivalence:

The **ABX MICROS 60** is based on the same fundamental technology as the predicate devices cleared to market under K014203.

The use of a predicate device to show the clinical capability was ABBOTT CD 4000 (K961439).

Description:

The **ABX MICROS 60** device is a benchtop, clinical laboratory instruments that analyze *in-vitro* samples of whole blood specimens. The device operates in a complete blood count (CBC) and 3 part DIFF (LMG). As either a closed tube / closed system (CT/CS) or open tube/open system (OT/OS). The ABX MICROS 60 can evaluate 5,8, 16 or 18 hematology parameters depending on its internal configuration.

Intended Use :

The **ABX MICROS 60** is a fully automated (microprocessor controlled) multi-parameter hematology analyzer intended for in *in-vitro* diagnostic use in the clinical laboratory environment.

Compared to the previous 510k submissions, there is no change to the intended use

Determination of substantial equivalence :

The **ABX MICROS 60** the released software version 1.6 is substantially equivalent to the already cleared device MICROS 60 v1.4 (K992511) with respect to the indications for use, the hematological parameters for complete blood count and 3 part differential leucocyte count, and the principles of operation (fundamental scientific technology).

Discussion of Performance Data:

This submission is carried out in accordance with appropriate indications given by the FDA guidelines.

The data presented in this 510K Pre-market Notification demonstrate good precision in accordance with EP5-A (NCCLS guidelines) and is entirely acceptable for all parameters. No change to the claimed limits is being made in this submission.

The linearity claim for the parameters WBC ($0-100 \times 10^3 / \text{mm}^3$), RBC ($0 - 8.0 \times 10^6 / \text{mm}^3$), HGB($0 - 26\text{g/dl}$), HCT ($0 - 80\%$), PLT with Hgb $>2\text{g/dl}$ ($0 - 2,200 \times 10^3 / \text{mm}^3$)

and PLT with Hgb<2g/dl ($0 - 4000 \times 10^3 / \text{mm}^3$) are entirely supported by the clinical data provided in this submission.

Accuracy (Inter-procedural Correlation) demonstrated no evidence of significant bias between the MICROS 60 and the Abbott CD 4000 provided good correlation of $R^2 > 0.95$ for all parameters. No change to the claimed limits is being made in this submission.

The clinical studies conclude that the safety and effectiveness of the devices is not compromised.

Conclusions for non clinical and clinical tests :

The clinical studies tests conclude that the safety and effectiveness of the device is not compromised. Clinical testing met all acceptance criteria.

The device meets with the IEC 1010-1 standard of the International Electro-technical Commission on electrical equipment for measurement, control, and laboratory use. As well as the EN 61326 standard for Electromagnetic Compatibility.

All clinical and non clinical tests show appropriate levels of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 08 2003

Mr. Tim Lawton
Regulatory Affairs Manager
ABX Diagnostics
Parc Euromedecine
Rue du Caducee - BP 7290
34184 Montpellier cedex 4
FRANCE

Re: k030799
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: March 7, 2003
Received: March 13, 2003

Dear Mr. Lawton:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

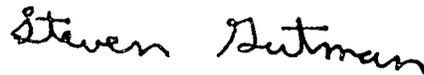
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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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 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 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 (301) 594-3084. 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/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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure



MICROS 60

Special 510(k): Device Modification

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

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 OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 030799