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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 : K024003

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

Date Prepared: November 27th, 2002

Device Name:

Trade/Proprietary Name:	**ABX PENTRA 80 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 PENTRA 80** based on the same fundamental technology as the predicate device **ABX PENTRA 60C+** cleared to market under K003677.

The use of a second predicate device to show its clinical capability compatibility was used ABBOTT CD 4000 (K961439).

Description:
The **PENTRA 80** 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, with an internal PC that performs further data processing and hosts the user interface.

Intended Use :

The **PENTRA 80** is fully automated (microprocessor controlled) multi-parameter hematology analyzer intended for in *in-vitro* diagnostic use in the clinical laboratory environment.

Determination of substantial equivalence :

The **PENTRA 80** is substantially equivalent to the already cleared device PENTRA 60C+ with respect to the indications for use, the hematological parameters for complete blood count and differential leukocyte count, and the principles of operation (fundamental scientific technology).

Discussion of Performance Data:

The studies and data analysis were 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 available parameters.

The linearity claim for the parameters WBC (0-120 x $10^3/\mu L$), RBC (0 – 8.0 x $10^6/\mu L$), HGB(0 – 24g/dl), HCT (0 – 67%), PLT with Hgb>2g/l (0 - 1,900 x $10^3/\mu L$) and PLT with Hgb<2g/l (0 – 2800 x $10^3/\mu L$) are entirely supported by the clinical data provided in this submission.

Accuracy (Inter-procedural Correlation) showed no evidence of significant bias between the PENTRA 80 and the Abbott CD 4000 provided good correlation of $R^2>0.95$ for WBC, PLT, RBC, HGB, HCT parameters.

Leukocyte Differentiation provided good results on the differentiation between true & false positives and true & false negatives.

This study data assures a relative sample stability over a 48 hour period at 4°C.

No effect of contamination of the instrument was dissimulated by the clinical data of this study, supporting a Carry Over claim of <2% for WBC, RBC, HGB, PLT.

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

Mr. Tim Lawton
Regulatory Affairs Manager
ABX
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FRANCE

JAN 0 3 2003

Re: k024002
Trade/Device Name: ABX PENTRA 80 Hematology Analyzers
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: November 29, 2002
Received: December 4, 2002

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).

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). 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: **ABX PENTRA 80 Hematology Analyzers**

Indications For Use:

The **ABX PENTRA 80 Hematology Analyzer** is a fully automated (microprocessor controlled) hematology analyzer used for the *in vitro* diagnostic testing of whole blood specimens.

The **ABX PENTRA 80** is able to operate either in complete blood count (CBC) mode or in CBC + 5 differential leucocyte count (5DIFF) 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 CRFR 801.109)

J Reeves for S. Baptiste
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024002