JUL 2 9 2002

Premarket Notification [510(k)] Summary

ABX Diagnostics
Parc Euromédecine
Rue du Caducée - BP 7290
34184 Montpellier cedex 4 - France
Tél. : 33 (0) 4 67 14 15 16
Fax : 33 (0) 4 67 14 15 17

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 : K022200

Company: ABX Diagnostics
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
FRANCE
Telephone: + (33) 4 67 14 73 20
Fax: + (33) 4 67 14 15 17

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

Date Prepared: June 28, 2002

Device Name:

Trade/Proprietary Name:	**ABX PENTRA 120/120 RETIC Hematology Analyzers**
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

Optional device name :

Trade/Proprietary Name:	**SPS (Slide Preparation System)**
Common or Usual Name:	Slide Preparation System
Device Class	Class I : exempt
Classification Name:	Automated Slide Stainer : §864.3800 Automated Slide Spinner : §864.5850
Product Code:	KPA GKJ

Substantial Equivalence:

The **ABX PENTRA 120** (version 4.50) is a modification to the predicate **device ABX PENTRA 120** cleared to market under K962633, K990311 and K991839.

The optional device **SPS** (Slide Preparation System) has a substantially equivalent predicate device Coulter GEN-S SM^{TM} Integrated Slide Maker cleared to market under K962988.

The modification to the extension of the linearity range for white blood cells on whole blood and for platelets on the **ABX PENTRA 120** used two predicate devices:

ABBOTT CD 4000 (K961439) : for the leukocyte extension to linearity
BAKER 9110 Plus (K953598) : for the platelet count extension to linearity

Description:

The PENTA 120 / P120 RETIC Automated Hematology Analyzer is a bench-top, clinical laboratory instrument which analyzes in-vitro samples of whole blood to provide complete blood count, leukocyte differential count and reticulocyte count using principles of cytochemistry, focused flow impedance, light absorbance and fluorescence. The instrument is microprocessor driven.
Controlled by the PENTRA 120 the optional device **SPS** (Slide Preparation System) smears and stains the slides.

Intended Use :

ABX PENTRA Hematology Analyzer is an automated hematology analyzer providing complete blood count (CBC), differential leucocyte count (DIFF). The PENTRA 120 RETIC provides in addition a reticulocyte count (RET); specifically the immature reticulocyte fraction (IRF) to monitor erythropoietic activity in patients.
The option of the **SPS (Slide Preparation System)** is used to smear a blood film and to stain it on a clean microscope slide for microscope examination.

The instrument is for *in vitro* diagnostic use in clinical laboratories.

Determination of substantial equivalence :

The **ABX PENTRA 120** in this submission is substantially equivalent to the predicate device.

The following modifications to parameters and additional features have been made :

- Increase of the upper linearity ranges for white blood cells (WBC) on whole blood and for platelets (PLT)
- Optional module interfacing with the **SPS** (slide-preparation system) automated slide-stainer
- Miscellaneous software corrections

The optional device **SPS** (Slide Preparation System) is the same intended use as the predicate device to Coulter GEN-S^{TM} SM System (K962988). Both systems aspire on-line the blood sample from the analyzer enabling slide preparation : smearing, staining and slide identification.

Discussion of Performance Data:

The data presented in this submission demonstrates good precision as assessed by NCCLS EP5-A.

Total Imprecision ranged from between 1.1 and 3.9 CV% for Leukocytes, and 3.1 to 7.4 CV% for Platelet counting.

Accuracy / bias assessment (NCCLS EP 9-A) showed no evidence of significant bias. Good correlation was demonstrated between the PENTRA 120 and the Abbott CD 4000 for leukocyte enumeration (R^2=0.995) for all WBC results compared. Similarly, the correlation for platelet counting between the PENTRA 120 and the Baker 9110 Plus was excellent (R^2=0.99) for all platelet results compared.

Linearity assessment data supports a Total White Cell count linearity claim increase of upto 150 X $10^3/\mu L$; and a Platelet count linearity range up to 2000 X $10^3/\mu L$. This data was generated according to FDA guidelines.

The data presented in this submission for the option SPS (Slide Preparation System) demonstrated that the correlation of the results obtained between the manual and the SPS method is excellent. All the pathologies were correctly identified.

Conclusions for non clinical and clinical tests :

The clinical testing for the PENTRA 120 concerning the WBC and PLT focused on linearity, accuracy and precision. Whilst the clinical testing on the SPS (Slide Preparation System) focused on the accuracy between the manual method of smearing slides and those obtained with the SPS (Slide Preparation System).

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.

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 Diagnostics
Parc Euromedecine
Rue du Caducee – BP 7290
34184 Montpellier cedex 4
FRANCE

JUL 2 9 2002

Re: k022200
Trade/Device Name: ABX PENTRA 120/120 RETIC Hematology Analyzers
Option: Slide Preparation System (SPS)
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ, GKJ, KPA
Dated: June 28, 2002
Received: July 5, 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 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

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): K022200

Device Name: **ABX PENTRA 120/120 RETIC Hematology Analyzers**
Option : SPS (Slide Preparation System)

Indications For Use:

The **ABX PENTRA 120 Hematology Analyzer** is an automated hematology analyzer providing complete blood count (CBC) and differential leucocyte count (DIFF) for the *in vitro* diagnostic use in clinical laboratories.

The **ABX PENTRA 120 RETIC Hematology Analyzer** is an automated hematology analyzer providing complete blood count (CBC), differential leucocyte count (DIFF) as well as reticulocyte count (RET) for the *in vitro* diagnostic use in clinical laboratories. The clinical use in the **ABX PENTRA 120 RETIC Hematology Analyzer** of the reticulocyte count, specifically the immature reticulocyte fraction (IRF), is to monitor erythropoietic activity in patients.

The option of the **SPS (Slide Preparation System)** smears and stains on a clean microscope slide.

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022200