APR 26 2005

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 : K050719

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

Date Prepared: 14th March 2005

Device Name:

Trade/Proprietary Name:	**ABX PENTRA DX 120 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

Optional device name :

Trade/Proprietary Name:	**SPS Evolution (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 DX 120 is considered comparable to the predicate device ABX PENTRA 120 cleared to market under K962633, K990311, K991839 and K022200.

The fundamental scientific technology for the analyzer itself has not changed. Including, hematological parameters for complete blood count, differential leucocyte count, reticulocyte counting, the reagents and controls, measuring principles, and the principles of operation are the same as previously cleared by the FDA.

Whilst the SPS Evolution (Slide Preparation System) is considered substantially equivalent to the SPS used on the ABX PENTRA 120.

For the validation of the NRBC parameter on the ABX PENTRA DX 120 the following different predicate devices were used during the clinical evaluation of the NRBC parameter :

ABBOTT CD 4000 (K961439)
SYSMEX XE-2100 (K992875)

Description:

The PENTRA DX 120 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, reticulocyte and NRBC 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 Evolution (Slide Preparation System) smears and stains the slides.

Intended Use :

The ABX PENTRA DX 120 Hematology Analyzer is an automated hematology analyzer providing complete blood count (CBC), differential leucocyte count (DIFF) as well as reticulocyte count (RET), and nucleated red blood cell count (NRBC) for the in vitro diagnostic use in clinical laboratories.

The clinical use of the reticulocyte count, specifically the immature reticulocyte fraction (IRF), is to monitor erythropoietic activity in patients.

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

Determination of substantial equivalence :

The ABX PENTRA DX 120 in this submission is substantially equivalent to the predicate device the ABX PENTRA 120 with respect to the indications for use, the hematological parameters for complete blood count (CBC), differential leucocyte count (DIFF) as well as reticulocyte count (RET), and the principles of operation (fundamental scientific technology).

The ABX PENTRA DX 120 provides an additional parameter, the nucleated red blood cell count (NRBC) having comparable measurement techniques of nucleic acid fluorescence to both predicate devices.

Discussion of Performance Data:

The studies and data analysis carried out in accordance with appropriate indications given by the FDA guidelines were compiled to support the claims in this submission.

NRBC :
The data presented in this 510K Pre-market Notification demonstrate good precision in accordance with EP5-A (NCCLS guidelines) and is entirely acceptable for the NRBC.

The linearity limits claim for the NRBC/100 WBC Count parameter are entirely supported by the clinical data provided in this submission.

Accuracy (Inter-procedural Correlation) showed no evidence of significant bias between the HoribaABX PENTRA DX 120 and the Abbott CD 4000, Sysmex XE-2100, and multiparameter flow cytometry with r^2 ranging between 0.96 - 0.98.

The HoribaABX Pentra DX120 provided good results on the differentiation between true & false positives and true & false negatives, comparable to other predicate systems.

This study data assures a relative sample stability over a 24 hour period at both room temperature and 4°C.

No effect of contamination of the instrument was dissimulated by the clinical data of this study, supporting a Carry Over claim of <1%.

Platelet parameter :
The submission supports an extended range claim for Platelets with Hgb<2g/dl of 0 – 2800 x10^6/mm^3.

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 61010-1 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 26 2005

Mr. Tim Lawton
Regulatory Affairs Manager
Horiba ABX
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FRANCE

Re: k050719
Trade/Device Name: ABX PENTRA DX 120 Hematology Analyzer
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated cell counter and differential cell counter
Regulatory Class: II
Product Code: GKZ, KPA, GKJ
Dated: March 14, 2005
Received: March 21, 2005

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 (240) 276-0484. 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/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
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 DX 120 Hematology Analyzer**
Option : SPS Evolution (Slide Preparation System)

Indications For Use:

The **ABX PENTRA DX 120 Hematology Analyzer** is an automated hematology analyzer providing complete blood count (CBC), differential leucocyte count (DIFF) as well as reticulocyte count (RET), and nucleated red blood cell count (NRBC) for the *in vitro* diagnostic use in clinical laboratories.

The clinical use of the reticulocyte count, specifically the immature reticulocyte fraction (IRF), is to monitor erythropoietic activity in patients.

The option of the **SPS Evolution (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)

Josephine Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K050719
~~HORIBA ABX, FRANCE~~