

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

K050719

B. Purpose for Submission:

510(k) for the addition of a new parameter for nucleated red blood cell count (NRBC), and an optional slide smearing and staining unit known as the SPS Evolution.

C. Manufacturer and Instrument Name:

Horiba ABX Pentra DX 120 Hematology Analyzer

D. Type of Test or Tests Performed:

Quantitative

E. System Descriptions:

1. Device Description:

The ABX PENTRA DX 120 Automated Hematology Analyzer is an *in vitro*, bench-top, clinical laboratory instrument, providing a complete blood count (CBC), leukocyte differential count (DIFF), reticulocyte count (RET), and nucleated red blood cell count (NRBC). The optional slide preparation system (SPS Evolution) smears and stains slides.

2. Principles of Operation:

The instrument is driven by a microprocessor, and uses cytochemistry, focused flow impedance, light absorbance, and fluorescence methodologies.

3. Modes of Operation:

Automatic, open (stat mode)/closed tube modes

4. Specimen Identification:

By keyboard and internal and external barcode

1. Specimen Sampling and Handling:

Manual-

1. Aspiration of 130 µl of blood through the shear valve
2. The Blood samples goes to detection cell, which triggers the sampling valve switch.
3. Blood volumes contained in the valve loops are transferred to the measurement chambers
4. Internal and external needle rinse

Automatic

1. Cassette mixed
2. Cassette identification and tube detection
3. Tube extraction from the cassette and cap piercing
4. Aspiration of 200µl of blood
5. Aspiration of specimen through the commutation valve
6. The Blood samples goes to detection cell, which triggers the sampling valve switch.
7. Blood volumes contained in the valve loops are transferred to the measurement chambers
8. Internal and external needle rinse

Calibration:

Commercially available calibration material

7. Quality Control:

Electronic quality control (EQC) and external liquid controls

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes or No

F. Regulatory Information:

1. Regulation section:

- 21 CFR 864.5200
- 21 CFR 864.5220
- 21 CFR 864.3800
- 21 CFR 864.5850

2. Classification:

Automated cell counter and differential cell counter – Class II

Slide stainer and slide spinner - Class I

3. Product code:

GKZ, KPA, GKJ

4. Panel:

81 Hematology

G. Intended Use:

1. Indication(s) for Use:

The Horiba ABX, Pentra DX 120/Pentra DX 120 SPS Evolution, is a fully automated hematology analyzer used for the *in vitro* diagnostic testing of whole blood specimens.

2. Special Conditions for Use Statement(s):

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

ABX PENTRA 120 (K962633, K990311, K991839, K022200)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	A fully automated hematology analyzer providing complete blood count, differential leucocyte count, retic count, immature reticulocyte fraction and nucleated red blood cell count	Same without the nucleated red blood cell count
Parameters	CBC, DIFF, RET	Same
Principles of operation	cytochemistry, focused flow impedance, light	Same

Similarities		
Item	Device	Predicate
	absorbance, and fluorescence methodologies	

Differences		
Item	Device	Predicate
New Parameter	NRBC	Not available
Slide drying Principal	Verticalyser which allows for natural air drying	Halogen lamp

I. Special Control/Guidance Document Referenced (if applicable):

Evaluation of Precision Performance of Clinical Chemistry Devices; approved Guideline, NCCLS document EP5-A (ISBN 1-56238-145-8) 1999

Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, NCCLS document EP9-A2 (ISBN 1-56238-283-7), 2002

Reference Leukocyte Differential (Proportional) and Evaluation of Instrumental Methods, Approved Standard, NCCLS document H20-A (ISBN 1-56238-131-8), 1992

Guidelines for the evaluation of blood cell analysers including those used for differential leukocyte and reticulocyte counting and cell marker applications. International Council for Standardization in Hematology; Clinical Lab. Haemat. 1994, 16,157-174.

Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA Document, 2001

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

b. Precision/Reproducibility:

c. Linearity:

d. Carryover:

e. Interfering Substances:

2. Other Supportive Instrument Performance Data Not Covered Above:

As required for a Special 510(k), the Sponsor has provided a risk analysis as well as a Declaration of Conformity with Design Controls indicating that development activities were conducted under appropriate design controls procedures, and the overall product specifications were met.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.