Premarket Notification [510(k)] Summary

OCT 17 2008

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 : K073309

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Date Prepared: 24th June 2008

Device Names:
The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA HbA1c WB**
Common or Usual Name:	Hemoglobin A1c
Device Class	Class II
Classification Name:	§864.7470 : Glycosylated hemoglobin assay
Product Code:	LCP ; Assay, Glycosylated hemoglobin

CALIBRATOR:

Trade/Proprietary Name:	**ABX PENTRA HbA1c WB Cal**
Common or Usual Name:	HbA1c Calibrator
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-analyte mixture

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA HbA1c WB Control**
Common or Usual Name:	Hemoglobin A1c Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-analyte controls (Assayed and Unassayed)

ADDITIONAL REAGENTS:

Trade/Proprietary Name:	**ABX PENTRA HbA1c WB Hemolysis Reagent**
Common or Usual Name:	Hemolysis reagent
Device Class	Class I : Exempt from Premarket notification
Classification Name:	§862.8540 : Red cell lysing product
Product Code:	GGK ; Products, Red-cell lysing products

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :

Submission device	Substantially equivalent Predicate device
ABX PENTRA HbA1c WB	K031380 (Olympus) K955087 (Bayer)
ABX PENTRA HbA1c Cal	K031380 (Olympus) K955087 (Bayer)
ABX PENTRA HbA1c Control	K031380 (Olympus) K951361 (Bayer)

Description:

All the reagents, controls and calibrators included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA HbA1c WB** is an in vitro diagnostic assay for the quantitative determination of Hemoglobin A1c in human whole blood based on a turbidimetric and colorimetric test. The assay is composed of the following vials:
1 x 23 ml vial (R1)
1 x 23 ml vial (R2)
1 x 110 ml vial (R3)
2 x 21 ml vials (R4)
1 x 25 ml vial (R5)

Reagent R1 is prepared from substances of animal origin and purified with human material. Reagents R2 and R3 are prepared from substances of animal origin and chemical solutions. R4 and R5 are chemical solutions with additives.

The **ABX PENTRA HbA1c Cal** is a liquid multi-calibrator prepared from chemical solutions. It is used for the calibration of the HbA1c assays. The assigned values are given in the notice. This calibrator has six levels and is provided in one vial of 8 ml and five vials of 2 ml.

The **ABX PENTRA HbA1c Control** is a lyophilized assayed control prepared from human whole blood. It has 2 levels (Normal and Pathological) to be used for the quality control of HbA1c assays. The assigned values are given in the enclosed annex. Each level of this calibrator is provided in two vials of 0.25 ml. The kit contains also a 2 ml reconstitution buffer vial.

The **ABX PENTRA HbA1c WB Hemolysis Reagent** is a chemical solution for use in the lysis of red blood cells with the HbA1c HORIBA ABX methods on the ABX Pentra 400 system. It is provided in a 110 ml vial.

Intended Use:

ABX Pentra HbA1c WB reagent is intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of HbA1c using whole blood and hemolysate.
The controls, calibrators and additional reagents are intended for use in association with the above reagents.

Discussion of Performance Data:

REAGENT

ABX PENTRA HbA1c WB (Hemolysate/Manual hemolysis method) :	
Sample type	Whole blood
Accuracy and Precision	CV Total < 2.72%
Linearity	For Total Hemoglobin : 2.07 g/dl – 20.00 g/dl For HbA1c : 0.16 g/dl – 2.85 g/dl
Measuring range	For HbA1c % : 4.98 % - 15.16 %
Correlation (n=144)	Y = 0.97 x + 0.36 with a correlation coefficient r^2 = 0.9673
Calibration stability	3 weeks
Reagent stability	closed stability: 24 months at 2-8°C open stability of the reagents : up to the expiration date at 2-8°C stability after reconstitution of the latex antibody complex : 2 months at 2-8°C

ABX PENTRA HbA1c WB (Whole Blood/Automated hemolysis method) :	
Sample type	Whole blood
Accuracy and Precision	CV Total < 3.71%
Linearity	For Total Hemoglobin : 105 g/dl – 1027 g/dl For HbA1c : 8.13 g/dl – 145.3 g/dl
Measuring range	For HbA1c % : 4.98 % - 15.16 %
Correlation (n=144)	Y = 0.98 x + 0.41 with a correlation coefficient r^2 = 0.9561
Calibration stability	3 weeks
Reagent stability	closed stability: 24 months at 2-8°C open stability of the reagents : up to the expiration date at 2-8°C stability after reconstitution of the latex antibody complex : 2 months at 2-8°C

CALIBRATOR

ABX PENTRA HbA1c Cal:	
Analytes	Hemoglobin A1c Total Hemoglobin
Format	Liquid chemical solutions
Stability	Closed stability: 24 months Open stability: until the expiry date when stored at 2°C to 8°C

CONTROLS

ABX PENTRA HbA1c Control :	
Analytes	Hemoglobin A1c % : 2 levels (normal and pathological)
Format	Lyophilized preparation of human whole blood
Stability	Closed stability: 36 months Open stability after reconstitution: 3 months at 2°C to 8°C

ADDITIONAL REAGENT

ABX PENTRA HbA1c WB Hemolysis Reagent:	
Analyte	HbA1c assays
Format	Chemical hemolysing solution
Stability	Closed stability: 18 months Open stability : until the expiry date when stored at 2°C to 8°C

Conclusions for Performance Testing:
The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Horiba ABX SAS
c/o Mr. Olivier Ducamp
Regulatory Affairs Manager
Parc Euromédecine
Rue du Caducée – BP 7290
Montpellier, Hérault, France 34184

OCT 17 2008

Re: k073309
Trade/Device Name: HbA1c Reagent on the ABX Pentra Clinical Chemistry Analyzer
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JIX, JJY
Dated: September 30, 2008
Received: October 2, 2008

Dear Mr. Ducamp:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073309

Device Name: HbA1c reagent on ABX PENTRA Clinical Chemistry Analyzer

Indication For Use:

ABX PENTRA HBA1c WB reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of Hemoglobin A1c percentage (%HbA1c) in human whole blood based on a colorimetric and turbidimetric assay. It is intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer

Percent HbA1c measurements are used in the clinical management of diabetes to assess the long-term efficacy of diabetic control.

The ABX PENTRA HbA1c WB Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA HbA1c WB method on Horiba ABX clinical chemistry analyzers.

The ABX PENTRA HbA1c WB Control is for use in quality control by monitoring accuracy and precision for the quantitative ABX PENTRA HbA1c WB method.

The ABX PENTRA HbA1c WB Hemolysis Reagent is an additional reagent for use in combination for the quantitative ABX PENTRA HbA1c WB method.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073309