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 : K072115

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NOV 3 0 2007

Date Prepared: 26th July 2007

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 Creatinine 120 CP**
Common or Usual Name:	Creatinine
Device Class	Class II
Classification Name:	§862.1225 : Creatinine Test System
Product Code:	CGX ; alkaline picrate, colorimetry, creatinine

Trade/Proprietary Name:	**ABX PENTRA Total Protein 100 CP**
Common or Usual Name:	Total Protein
Device Class	Class II
Classification Name:	§862.1635 : Total Protein Test System
Product Code:	CEK ; Biuret (colorimetric) total protein

CALIBRATORS:

Trade/Proprietary Name:	**ABX PENTRA Multical** (K052007)
Common or Usual Name:	Multical
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA N Control** (K052007)
Common or Usual Name:	N Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Trade/Proprietary Name:	**ABX PENTRA P Control** (K052007)
Common or Usual Name:	P Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

Trade/Proprietary Name:	**ABX PENTRA Urine Control L/H** (K070249)
Common or Usual Name:	Urine control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

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 Creatinine 120 CP	K973869 (serum/plasma samples) K941837 (urine samples)
ABX PENTRA Total Protein 100 CP	K973869
ABX PENTRA Multical	K052007
ABX PENTRA N Control	K052007
ABX PENTRA P Control	K052007
ABX PENTRA Urine Control L/H	K070249

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 Creatinine 120 CP** is an in vitro diagnostic assay for the quantitative determination of creatinine in human serum, plasma and urine based on a kinetic method using alkaline picrate (Jaffé method). It is composed of a 27 ml mono-reagent cassette. Reagent is a chemical solution with additives.

The **ABX PENTRA Total Protein 100 CP** is an in vitro diagnostic assay for the quantitative determination of total proteins in human serum and plasma based on a colorimetric test (Biuret reaction). It is composed of a 28 ml mono-reagent cassette. Reagent is a chemical solution with additives.

The **ABX PENTRA Multical** is a lyophilized human serum calibrator with chemical additives and materials of biological origin. The assigned values of the calibrator components are given in the enclosed annex, ensuring optimal calibration of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer.
This calibrator is provided in ten vials of 3 ml.

The **ABX PENTRA N Control** and **ABX PENTRA P Control** are quality control products consisting of lyophilized human serum with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexes, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each control is provided in ten vials of 5 ml.

The **ABX PENTRA Urine Control L/H** is a two-level (Low and High) quality control consisting of liquid solutions prepared from human urine with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexe, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each control level is provided in one vial of 10 ml.

Intended Use :

All reagents in this submission are intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of their respective analytes (Creatinine, Total Protein) using human serum, plasma and/or urine.

The controls and calibrator are intended for use in association with the above reagents.

Discussion of Performance Data:

ABX PENTRA Creatinine 120 CP :	
Sample type	Serum, Plasma and Urine
Detection limit	Serum/Plasma : 0.18 mg/dl Urine : 1.39 mg/dl
Accuracy and Precision	Serum/Plasma CV Total < 5.83% Urine CV Total < 6.00%
Measuring range	Serum/Plasma : 0.18 mg/dl - 22.60 mg/dl Urine : 1.39 mg/dl - 282.5 mg/dl
Upper linearity limit	Serum/Plasma : 22.60 mg/dl, and with automatic post-dilution : 67.8 mg/dl Urine : 282.5 mg/dl, and with automatic post-dilution : 857.5 mg/dl
Correlation	Serum/Plasma (n=122) : $Y = 0.98 x - 0.04$ with $r^2 = 0.9991$ Urine (n=119) : $Y = 0.96 x - 0.73$ with $r^2 = 0.9975$
Calibration stability	Serum/Plasma : 24 hours Urine : 24 hours
Reagent stability	closed stability: 24 months at 2-8°C on-board stability : 10 days

ABX PENTRA Total Protein 100 CP :	
Sample type	Serum/Plasma
Detection limit	0.01 g/dl
Accuracy and Precision	CV Total < 1.62%
Measuring range	0.10 g/dl – 10.0 g/dl
Upper linearity limit	10.0 g/dl, and with automatic post-dilution : 20.0 g/dl
Correlation (n=178)	Y = 1.03 x – 0.20 with a correlation coefficient $r^2 = 0.9921$.
Calibration stability	1 day
Reagent stability	closed stability: 26 months at 2-25°C on-board stability (refrigerated area): 14 days

CALIBRATORS

ABX PENTRA Multical:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
Lipase	√	√
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Cholesterol	√	√
Creatinine	√	√
Creatinine 120		√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Total Protein	√	√
Total Protein 100		√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 24 months at 2-8°C Open stability: Once opened, the calibrator components** are stable for : 8 hours at 15°C to 25°C 2 days at 2°C to 8°C 2 weeks at –25°C to –15°C **Exceptions Direct Bilirubin 3 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 6 hours at 15°C to 25°C	

.../...

ABX PENTRA Multical:	
	1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

CONTROLS

ABX PENTRA N Control:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
Lipase	√	√
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Chloride	√	√
Cholesterol	√	√
HDL	√	√
LDL	√	√
Creatinine	√	√
Creatinine 120		√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Potassium	√	√
Sodium	√	√
Total Protein	√	√
Total Protein 100		√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
		.../...
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 30 months at 2-8°C	

ABX PENTRA N Control:	
	Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

ABX PENTRA P Control:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180, K062737, K060434)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase	√	√
GGT	√	√
Lipase	√	√
Albumin	√	√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Chloride	√	√
Cholesterol	√	√
HDL	√	√
LDL	√	√
Creatinine	√	√
Creatinine 120		√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Potassium	√	√
Sodium	√	√
Total Protein	√	
Total Protein 100		√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C …/… **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C	

ABX PENTRA P Control:	
	8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

ABX PENTRA Urine Control L/H:		
Analytes	Already cleared (K070249)	Included in this submission
Amylase	√	√
Calcium	√	√
Creatinine	√	√
Creatinine 120		√
Phosphorus	√	√
Glucose*		
Urea / Blood Urea Nitrogen*		
Uric acid*		
Urinary proteins*		
Format	Liquid solution prepared from human urine with chemical additives and materials of biological origin	
Stability	Closed stability: 2 years at 2-8°C Open stability: 30 days at 2-8°C	

* Not cleared as of date of submission

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

NOV 3 0 2007

Horiba ABX
c/o Olivier DUCAMP
Regulatory Affairs Manager
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4, France

Re: k072115
Trade Name: ABX PENTRA Creatinine 120 CP Reagent, ABX PENTRA Total Protein 100 CP Reagent, ABX PENTRA Multical, ABX PENTRA N Control, ABX PENTRA P Control, ABX PENTRA Urine Control L/H
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system.
Regulatory Class: Class II
Product Codes: CGX, CEK, JIX, JJY
Dated: November 07, 2007
Received: November 13, 2007

Dear Olivier 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): K072115

Device Name: New Creatinine and Total Protein on ABX PENTRA 400 Clinical Chemistry Analyzer

Indication For Use:

Creatinine and Total Protein reagents, with associated calibrators and controls, are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer to measure a variety of analytes.

ABX PENTRA Creatinine 120 CP reagent, with associated calibrator and controls, is a diagnostic reagent for quantitative in vitro determination of Creatinine in human serum, plasma and urine based on a kinetic method using alkaline picrate (Jaffé method). Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

ABX PENTRA Total Protein 100 CP reagent, with associated calibrator and controls, is a diagnostic reagent for quantitative in-vitro determination of Total Proteins in serum and plasma by colorimetry.
Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

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)

Carol C. Benson

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

510(k) K072115

Indication for Use

510(k) Number (if known): K072115

Device Name: ABX PENTRA Multical

Indication For Use:

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba ABX methods on Horiba ABX clinical chemistry analyzers.

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

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

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072115

Indication for Use

510(k) Number (if known): K072115

Device Name: ABX PENTRA N Control

Indication For Use:

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision.

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

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072115

Indication for Use

510(k) Number (if known): K072115

Device Name: ABX PENTRA P Control

Indication For Use:

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision.

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

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072115

Indication for Use

510(k) Number (if known): K072115

Device Name: ABX PENTRA Urine Control L/H

Indication For Use:

The ABX PENTRA Urine Control L/H is for use in quality control by monitoring accuracy and precision.

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

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