Premarket Notification [510(k)] Summary

JUL 2 1 2006

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 : K060205

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Date Prepared: 20th January 2006

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 ALP CP**
Common or Usual Name:	ALP - Alkaline phosphatase
Device Class	Class II
Classification Name:	§862.1050 : Alkaline phosphatase Test System
Product Code:	CJE ; nitrophenylphosphate, alkaline phosphatase or isoenzymes

Trade/Proprietary Name:	**ABX PENTRA Calcium CP**
Common or Usual Name:	Calcium
Device Class	Class II
Classification Name:	§862.1145 : Calcium Test System
Product Code:	CIC ; cresolphthalein complexone, calcium

Trade/Proprietary Name:	**ABX PENTRA CO2 RTU**
Common or Usual Name:	carbon dioxide
Device Class	Class II
Classification Name:	§862.1160 : Bicarbonate/carbon dioxide Test System
Product Code:	KHS ; enzymatic, carbon-dioxide

Trade/Proprietary Name: **ABX PENTRA Creatinine 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 Iron CP**
Common or Usual Name: Iron
Device Class: Class I
Classification Name: §862.1410 : Iron (non-heme) Test System
Product Code: JIY ; photometric method, iron (non-heme)

Trade/Proprietary Name: **ABX PENTRA Magnesium RTU**
Common or Usual Name: Magnesium
Device Class: Class II
Classification Name: §862.1495 : Magnesium Test System
Product Code: JGJ ; photometric method, magnesium

Trade/Proprietary Name: **ABX PENTRA Phosphorus CP**
Common or Usual Name: Phosphorus
Device Class: Class II
Classification Name: §862.1580 : Phosphorus (inorganic) Test System
Product Code: CEO ; phosphomolybdate (colorimetric), inorganic phosphorus

Trade/Proprietary Name: **ABX PENTRA Urea CP**
Common or Usual Name: Urea
Device Class: Class II
Classification Name: §862.1770 : Urea nitrogen Test System
Product Code: CDQ ; urease and glutamic dehydrogenase, urea nitrogen

Trade/Proprietary Name: **ABX PENTRA Uric Acid CP**
Common or Usual Name: Uric Acid
Device Class: Class I
Classification Name: §862.1775 : Uric acid Test System
Product Code: KNK ; acid, uric, uricase (colorimetric)

CONTROLS :

Trade/Proprietary Name: **ABX PENTRA CO2 Control**
Common or Usual Name: CO2 Control
Device Class: Class I
Classification Name: §862.1660 : Quality control material (assayed and unassayed)
Product Code: JJX ; single (specified) analyte controls (assayed and unassayed)

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 and unassayed)
Product Code: JJY ; Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

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 and unassayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

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

Trade/Proprietary Name:	**ABX PENTRA CO2 Cal**
Common or Usual Name:	CO2 Calibrator
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIT ; calibrator, secondary

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 ALP CP	K801242
ABX PENTRA Calcium CP	K883453
ABX PENTRA CO2 RTU	K031879
ABX PENTRA Creatinine CP	K941837
ABX PENTRA Iron CP	K864819
ABX PENTRA Magnesium RTU	K901758
ABX PENTRA Phosphorus CP	K883962
ABX PENTRA Urea CP	K954000
ABX PENTRA Uric Acid CP	K922762
ABX PENTRA CO2 Cal	K031879
ABX PENTRA CO2 Control	K891475

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 400** offers both Closed and Open channels for a multitude of parameters (clinical chemistry, DAT, TDM, plasma protein, hemostasis, optional ISE module).

All reagents described in this submission are for the quantitative in-vitro determination of their respective parameters

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 (ALP – Alkaline Phosphatase, Calcium, C02, Creatinine, Iron, Magnesium, Phosphorus, Urea / Blood Urea Nitrogen, Uric Acid) using human serum and plasma.
The controls and calibrators are intended for use in association with the above reagents.

Discussion of Performance Data:

ABX PENTRA ALP CP :	
Sample type	Serum & plasma
Detection limit	6 U/l
Accuracy and Precision	CV Total < 4.36%
Measuring range	6 U/l – 1500 U/l Automatic post-dilution : 6000 U/l
Correlation (n=105)	Y = 1.07 x - 3.93 with a correlation coefficient r^2 = 0.998.
Calibration stability	7 hours
Reagent stability	closed stability: 18 months at 2-8°C on-board stability (refrigerated area): 29 days

ABX PENTRA Calcium CP :	
Sample type	Serum & plasma
Detection limit	0.16 mg/dl
Accuracy and Precision	CV Total < 1.67%

ABX PENTRA Calcium CP :	
Measuring range	0.16 mg/dl – 20.1 mg/dl Automatic post-dilution : 40.2 mg/dl
Correlation (n=95)	Y = 1.15 x - 1.12 with a correlation coefficient $r^2 = 0.950$.
Calibration stability	6 hours
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 14 days

ABX PENTRA CO_2 RTU :	
Sample type	Serum & plasma
Detection limit	1.8 mmol/l
Accuracy and Precision	CV Total < 7.7%
Measuring range	1.8 mmol/l – 60.8 mmol/l Automatic post-dilution : 121.6 mmol/l
Correlation (n=97)	Y = 0.85 x + 0.3 with a correlation coefficient $r^2 = 0.976$.
Calibration stability	1 day
Reagent stability	closed stability: 16 months at 2-8°C on-board stability (refrigerated area): 28 days

ABX PENTRA Creatinine CP :	
Sample type	Serum & plasma
Detection limit	0.11 mg/dl
Accuracy and Precision	CV Total < 3.69%
Measuring range	0.11 mg/dl – 15.8 mg/dl Automatic post-dilution : 79 mg/dl
Correlation (n=95)	Y = 0.96 x – 0.12 with a correlation coefficient $r^2 = 0.996$.
Calibration stability	1 day
Reagent stability	closed stability: 36 months at 2-8°C on-board stability (refrigerated area): 7 days

ABX PENTRA Iron CP :	
Sample type	Serum & plasma
Detection limit	7.42 µg/dl
Accuracy and Precision	CV Total < 3.61%
Measuring range	7.42 µg/dl – 1004 µg/dl Automatic post-dilution : 5020 µg/dl
Correlation (n=98)	Y = 1.13 x + 5.30 with a correlation coefficient r^2 = 0.997.
Calibration stability	8 days
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 41 days

ABX PENTRA Magnesium RTU :	
Sample type	Serum & plasma
Detection limit	0.17 mg/dl
Accuracy and Precision	CV Total < 3.19%
Measuring range	0.17 mg/dl – 4.64 mg/dl Automatic post-dilution : 13.92 mg/dl
Correlation (n=75)	Y = 1.23 x - 0.24 with a correlation coefficient r^2 = 0.971.
Calibration stability	2 days
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 7 days

ABX PENTRA Phosphorus CP :	
Sample type	Serum & plasma
Detection limit	0.28 mg/dl
Accuracy and Precision	CV Total < 3.56%
Measuring range	0.28 mg/dl – 24.18 mg/dl Automatic post-dilution : 96.72 mg/dl
Correlation (n=105)	Y = 1.04 x + 0.19 with a correlation coefficient r^2 = 0.997.

ABX PENTRA Phosphorus CP :	
Calibration stability	34 days
Reagent stability	closed stability: 36 months at 2-8°C on-board stability (refrigerated area): 34 days

ABX PENTRA Urea CP :	
Sample type	Serum & plasma
Detection limit	Urea: 1.86 mg/dl BUN: 0.9 mg/dl
Accuracy and Precision	CV Total < 2.76%
Measuring range	Urea : 1.86 mg/dl – 300 mg/dl Automatic post-dilution: 1500 mg/dl BUN: 0.9 mg/dl – 140.3 mg/dl Automatic post-dilution : 701.5 mg/dl
Correlation (n=108)	Urea: Y = 1.01 x + 1.80 with a correlation coefficient r^2 = 0.9905. BUN: Y = 1.01 x + 0.81 with a correlation coefficient r^2 = 0.9905.
Calibration stability	8 days
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 70 days

ABX PENTRA Uric Acid CP :	
Sample type	Serum & plasma
Detection limit	0.19 mg/dl
Accuracy and Precision	CV Total < 2.81%
Measuring range	0.19 mg/dl – 25 mg/dl Automatic post-dilution : 75 mg/dl
Correlation (n=98)	Y = 0.97 x - 0.13 with a correlation coefficient r^2 = 0.958.
Calibration stability	15 days
Reagent stability	closed stability: 36 months at 2-8°C on-board stability (refrigerated area): 41 days

CALIBRATORS

ABX PENTRA CO2 Cal:	
Stability	closed stability: 15 months at 2-25°C open stability: 3 months at 2-25°C

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

CONTROLS

ABX PENTRA CO2 Control:	
Stability	Closed stability: 15 months at 2-25°C Open stability: 3 months at 2-25°C

ABX PENTRA N Control:	
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 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C

ABX PENTRA N Control:	
	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:	
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 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

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

Mr. Tim Lawton
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JUL 2 1 2006

Re: k060205
Trade/Device Name: General Chemistries on ABX PENTRA 400
Clinical Chemistry Analyzer
ABX PENTRA CO_2 Cal
ABX PENTRA CO_2 Control
Regulation Number: 21 CFR§ 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE, CIC, KHS, CGX, JIY, JGJ, CEO, CDQ, KNK, JJX, JJY, JIX, JIT
Dated: June 28, 2006
Received: June 30, 2006

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.

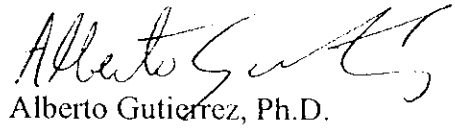
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060205

Device Name: General Chemistries on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

General Chemistries 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 ALP CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of alkaline phosphatase in human serum and plasma based on a kinetic photometric test using p-Nitrophenylphosphate. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

ABX PENTRA Calcium CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of calcium in human serum and plasma based on a photometric test using orthocresolphtalein complexone. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

ABX PENTRA CO_2 RTU reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of carbon dioxide in human serum and plasma based on an enzymatic test using phosphoenolpyruvate (PEP), phosphorenolpyruvate carboxylase (PEPC) and an analog of NADH. Bicarbonate/carbon measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060205

Indications for Use

510(k) Number (if known): K060205

Device Name: General Chemistries on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

ABX PENTRA Creatinine CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of creatinine in human serum and plasma 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 Iron CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of iron (non-heme) in human serum and plasma based on a photometric test (Ferene method). Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia and hemochromatosis.

ABX PENTRA Magnesium RTU reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of magnesium in human serum and plasma based on a photometric test using xylidyl blue. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060205

Indications for Use

510(k) Number (if known): K020205

Device Name: General Chemistries on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

ABX PENTRA Phosphorus CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of phosphorus in human serum and plasma based on a UV method using phosphomolybdate. Measurement of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

ABX PENTRA Urea CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of urea / urea nitrogen (an end-product of nitrogen metabolism) in human serum and plasma based on an enzymatic UV test using urease and glutamate dehydrogenase. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

ABX PENTRA Uric Acid CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of uric acid in human serum and plasma based on the enzymatic determination of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method). Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K020205

Indications for Use

510(k) Number (if known): K060205

Device Name: ABX PENTRA CO_2 Cal

Indications For Use:

The ABX PENTRA CO_2 Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA CO_2 RTU method on Horiba ABX clinical chemistry analyzers as specified on the vial.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Office of In Vitro Diagnostic Device Evaluation and Safety

K060205

Indications for Use

510(k) Number (if known): K060205

Device Name: ABX PENTRA CO_2 Control

Indications For Use:

The ABX PENTRA CO_2 Control is for use in quality control by monitoring accuracy and precision for the quantitative ABX PENTRA CO_2 RTU method as specified in the enclosed annex.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) K060205