Premarket Notification [510(k)] Summary

APR 26 2007

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 : K070249

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Date Prepared: 24th January 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 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 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 Phosphorus CP**
Common or Usual Name:	Phosphorus
Device Class	Class I
Classification Name:	§862.1580 : Phosphorus (inorganic) Test System
Product Code:	CEO ; phosphomolybdate (colorimetric), inorganic phosphorus

Trade/Proprietary Name:	**ABX PENTRA Amylase CP**
Common or Usual Name:	Amylase
Device Class	Class II
Classification Name:	§862.1070 : Amylase Test System
Product Code:	JFJ ; Catalytic methods, Amylase

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA Urine Control L/H**
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 Calcium CP	K896224
ABX PENTRA Creatinine CP	K941837
ABX PENTRA Phosphorus CP	K883962
ABX PENTRA Amylase CP	K972297
ABX PENTRA Urine Control L/H	K020817

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 Calcium CP** is an in vitro diagnostic assay for the quantitative determination of calcium in human serum, plasma and urine based on a photometric test using orthocresolphtalein complexone. It is composed of a bi-reagent cassette, with 66 ml and 16.5 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA Creatinine 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 bi-reagent cassette, with two 28 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA Phosphorus CP** is an in vitro diagnostic assay for the quantitative determination of phosphorus in human serum, plasma and urine based on a UV method using phosphomolybdate. It is composed of a mono-reagent cassette, with 29.5 ml compartment. The reagent is a chemical solution with additives.

The **ABX PENTRA Amylase CP** is an in vitro diagnostic assay for the quantitative determination of alpha-amylase in human serum, plasma and urine based on an enzymatic photometric test. The assay is composed of a bi-reagent cassette, with 26 ml and 6.5 ml compartments. Reagents are chemical solutions with additives.

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 (Calcium, Creatinine, Phosphorus, Amylase) using human serum, plasma and urine.

The controls, calibrators and additional reagents are intended for use in association with the above reagents.

Discussion of Performance Data:

ABX Pentra Calcium CP (K060205), ABX Pentra Creatinine CP (K060205), ABX Pentra Phosphorus CP (K060205) and ABX Amylase CP (K062180) have already been cleared by the FDA for use on serum and plasma samples. No modification has been made to these devices. The performances on serum and plasma samples have not been modified. Therefore, for these 4 devices, only added performances, on urine samples, are discussed below.

ABX PENTRA Calcium CP :	
Sample type	Urine
Detection limit	0.12 mg/dl
Accuracy and Precision	CV Total < 3.61%
Measuring range	0.12 mg/dl – 24.06 mg/dl
Upper linearity limit	24.06 mg/dl, and with automatic post-dilution : 48.12 mg/dl
Correlation (n=124)	Y = 1.13 x – 0.50 with a correlation coefficient $r^2 = 0.9904$.
Calibration stability	6 hours
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 14 days

ABX PENTRA Creatinine CP :	
Sample type	Urine
Detection limit	1.3 mg/dl
Accuracy and Precision	CV Total < 4.60%
Measuring range	1.3 mg/dl – 316.4 mg/dl
Upper linearity limit	316.4 mg/dl, and with automatic post-dilution : 949.2 mg/dl
Correlation (n=110)	Y = 0.99 x – 0.98 with a correlation coefficient $r^2 = 0.9953$.
Calibration stability	1 day
Reagent stability	closed stability: 36 months at 2-8°C on-board stability : 7 days

ABX PENTRA Phosphorus CP :	
Sample type	Urine
Detection limit	1.28 mg/dl
Accuracy and Precision	CV Total < 5.95%
Measuring range	1.28 mg/dl – 198.4 mg/dl
Upper linearity limit	198.4 mg/dl, and with automatic post-dilution : 396.8 mg/dl
Correlation (n=119)	Y = 1.07 x – 1.10 with a correlation coefficient $r^2 = 0.9892$.
Calibration stability	34 days
Reagent stability	closed stability: 36 months at 2-8°C on-board stability (refrigerated area): 34 days

ABX PENTRA Amylase CP :	
Sample type	Urine
Detection limit	4.92 U/l
Accuracy and Precision	CV Total < 6.03%
Measuring range	4.92 U/l – 2000 U/l
Upper linearity limit	2000 U/l, and with automatic post-dilution : 6000 U/l
Correlation (n=121)	Y = 1.17 x + 21.90 with a correlation coefficient $r^2 = 0.9891$.
Calibration stability	8 days
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 42 days

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Horiba ABX
c/o Pascal Macziola
Regulatory Affairs Manager
Parc Euromédecine, Rue Du Caducée - BP7290
34184 Montpellier cedex 4, France

APR 26 2007

Re: k070249
Trade/Device Name: ABX Pentra Calcium CP, ABX Pentra Creatinine CP, ABX Pentra Phosphorus CP, ABX Pentra Amylase CP & ABX Pentra Urine Control L/H
Regulation Number: 21 CFR§862.1145
Regulation Name: Calcium test system.
Regulatory Class: Class II
Product Code: CIC, CGX, CEO, JFJ, JJY
Dated: January 24, 2007
Received: January 26, 2007

Dear Pascal Macziola:

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

Indications for Use

510(k) Number (if known): K070249

Device Name: ABX PENTRA Calcium CP

Indications For Use:

ABX PENTRA Calcium CP reagent with associated calibrators and controls are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer for quantitative in vitro diagnostic determination of calcium in human serum, plasma and urine 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).

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

Carol C. Benson
Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K070249

Indications for Use

510(k) Number (if known): K070249

Device Name: ABX PENTRA Creatinine CP

Indications For Use:

ABX PENTRA Creatinine CP reagent with associated calibrators and controls are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer for quantitative in vitro diagnostic 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.

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

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Page 1 of 5

Office of In Vitro Diagnostic Device Evaluation and Safety

K070249

Indications for Use

510(k) Number (if known): K070249

Device Name: ABX PENTRA Phosphorus CP

Indications For Use:

ABX PENTRA Phosphorus CP reagent with associated calibrators and controls are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer for quantitative in vitro diagnostic determination of phosphorus in human serum, plasma and urine based on a UV method using phosphomolybdate. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

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

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Evaluation and Safety

K070249

Indications for Use

510(k) Number (if known): K070249

Device Name: ABX PENTRA Amylase CP

Indications For Use:

ABX PENTRA Amylase CP reagent with associated calibrators and controls are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer for quantitative in vitro diagnostic determination of the activity of the enzyme amylase in human serum, plasma and urine based on an enzymatic photometric assay.
Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

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

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510(k) K070249

Indications for Use

510(k) Number (if known): K070249

Device Name: ABX PENTRA Urine Control L/H

Indications 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 _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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