K081276

SEP 1 2 2008

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 : K081276

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Date Prepared: 03rd September 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 Glucose HK CP**
Common or Usual Name:	Glucose HK
Device Class	Class II
Classification Name:	§862.1345 : Glucose Test System
Product Code:	CFR; Hexokinase, Glucose

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 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-Analytc 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 Glucose HK CP	K944406
ABX PENTRA Uric Acid CP	K971485
ABX PENTRA Urine Control L/H	K070146

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 bench top clinical chemistry analyzer.

The **ABX PENTRA Glucose HK CP** is an in vitro diagnostic assay for the quantitative determination of glucose in human serum, plasma and urine based on an enzymatic method using hexokinase coupled with glucose-6-phosphate dehydrogenase. It is composed of a bi-reagent cassette, with 56 ml and 14 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA Uric Acid CP** is an in vitro diagnostic assay for the quantitative determination of uric acid in human serum, plasma and urine based on the enzymatic determination of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method). It is composed of a bi-reagent cassette, with 60 ml and 15 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 annex, 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 (Glucose, Uric Acid) using human serum, plasma and/or urine.
The controls and calibrators are intended for use in association with the above reagents.

Discussion of Performance Data:

ABX Pentra Glucose HK CP (K052007) and ABX Pentra Uric Acid CP (K060205) 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 2 devices, only added performances, on urine samples, are discussed below.

ABX PENTRA Glucose HK CP :	
Sample type	Urine
Limit of Blank Limit of Detection Limit of Quantitation	1.95 mg/dl 2.9 mg/dl 3.3 mg/dl
Accuracy and Precision	CV Total < 4.82%
Linearity	3.9 mg/dl – 900 mg/dl
Measuring range	3.9 mg/dl – 900 mg/dl, , and with automatic post-dilution : up to 2700 mg/dl
Correlation (n=208):	Y = 0.96 x + 0.84 mg/dl with a correlation coefficient $r^2 = 0.997$
Calibration stability	21 days
Reagent stability	closed stability: 36 months at 2-8°C on-board stability (refrigerated area): 55 days

ABX PENTRA Uric Acid CP :	
Sample type	Urine
Limit of Blank Limit of Detection Limit of Quantitation	2.33 mg/dl 3.49 mg/dl 5.20 mg/dl
Accuracy and Precision	CV Total < 4.36%
Linearity	5.20 mg/dl – 252 mg/dl
Measuring range	5.20 mg/dl – 252.00 mg/dl, , and with automatic post-dilution : up to 756.00 mg/dl
Correlation (n=226):	Y = 1.01 x + 0.99 mg/dl with a correlation coefficient $r^2 = 0.9949$
Calibration stability	15 days

ABX PENTRA Uric Acid CP :	
Reagent stability	closed stability: 36 months at 2-8°C on-board stability (refrigerated area): 41 days

CONTROLS

ABX PENTRA Urine Control L/H:		
Analytes	Already cleared	Included in this submission
Amylase	√ (K070249)	
Calcium	√ (K070249)	
Creatinine	√ (K070249)	
Phosphorus	√ (K070249)	
Glucose		√
Urea / Blood Urea Nitrogen	√ (K070146)	
Uric acid		√
Urinary proteins	√ (510k exempt)	
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

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HORIBA ABX Diagnostics
c/o Mr. Olivier Ducamp,
Regulatory Affairs Manager
Parc Euromedecine,
Rue du Caducee – BP 7290
34184 Montpellier cedex 4 France

Re: k081276
Trade/Device Name: ABX PENTRA Glucose HK CP, ABX PENTRA Uric Acid CP, ABX PENTRA Urine Control L/H
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code(s): CFR, KNK, JJY
Dated: August 13, 2008
Received: August 15, 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): K081276

Device Name: ABX PENTRA Glucose HK CP

Indication For Use:

ABX PENTRA Glucose HK CP reagent with associated calibrators and controls are intended for use on ABX PENTRA 400 for quantitative in vitro diagnostic determination of glucose in human serum, plasma and urine using glucose hexokinase method by colorimetry. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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

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Indication for Use

510(k) Number (if known): K081276

Device Name: ABX PENTRA Uric Acid CP

Indication For Use:

ABX PENTRA Uric Acid CP reagent with associated calibrators and controls are intended for use on ABX PENTRA 400 for quantitative in vitro diagnostic determination of uric acid in human serum, plasma and urine 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 ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

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Indication for Use

510(k) Number (if known): K081276

Device Name: ABX PENTRA Urine Control L/H

Indication For Use:

ABX PENTRA Urine Control L/H 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)

(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)

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