DEC 16 2005

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 : K052007

Company: Horiba ABX
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Contact Person: Tim Lawton (tlawton@fr.abx.fr)

Date Prepared: 16th November 2005

Device Name:

Trade/Proprietary Name:	**ABX PENTRA 400 Clinical Chemistry Analyzer**
Common or Usual Name:	Clinical Chemistry analyzer
Device Class	Class I : General Controls : Exempt from premarket.
Classification Name:	§862.2160 : Discrete photometric chemistry analyzer for clinical use
Product Code:	JJE

Trade/Proprietary Name:	**I.S.E Module (Optional)**
Common or Usual Name:	Ion Selective Electrode Option
Device Class	Class I : General Controls : Exempt from premarket.
Classification Name:	§862.2160 : Discrete photometric chemistry analyzer for clinical use
Product Code:	JJE

Electrodes :

Trade/Proprietary Name:	**ABX PENTRA Sodium-E**
Common or Usual Name:	Sodium Electrode
Device Class	Class II
Classification Name:	§862.1665 : Sodium Test System
Product Code:	JGS : electrode, ion specific, sodium

Trade/Proprietary Name:	**ABX PENTRA Chloride -E**
Common or Usual Name:	Chloride Electrode
Device Class	Class II
Classification Name:	§862.1170 : Chloride Test System
Product Code:	CGZ : electrode, ion-specific, chloride

Trade/Proprietary Name:	**ABX PENTRA Potassium -E**
Common or Usual Name:	Potassium Electrode
Device Class	Class II
Classification Name:	§862.1600 : Potassium Test System
Product Code:	CEM : electrode, ion specific, potassium

Trade/Proprietary Name:	**ABX PENTRA Reference -E**
Common or Usual Name:	Reference Electrode
Device Class	Class I : 510(k) exempt
Classification Name:	§862.2050 : General purpose laboratory equipment labeled or promoted
for a specific medical use	
Product Code:	JJP : electrode, ion specific (non-specified)

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 Glucose PAP CP**
Common or Usual Name:	Glucose PAP
Device Class	Class II
Classification Name:	§862.1345 : Glucose Test System
Product Code:	CGA ; Glucose Oxidase, Glucose

Calibrators :

Trade/Proprietary Name:	**ABX PENTRA Multical**
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 Standard 1**
Common or Usual Name:	Standard 1
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

Trade/Proprietary Name:	**ABX PENTRA Standard 2**
Common or Usual Name:	Standard 2
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

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

Controls :

Trade/Proprietary Name:	**ABX PENTRA N Control**
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**
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)

Cleaning solutions :

Trade/Proprietary Name:	**ABX PENTRA Clean-Chem CP**
Common or Usual Name:	Clean-Chem
Device Class	Class I : Exempt from Premarket Notification
Classification Name:	Not available
Product Code:	Not available

Trade/Proprietary Name:	**ABX PENTRA Clean-Chem 99 CP**
Common or Usual Name:	Clean-Chem 99
Device Class	Class I : exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Trade/Proprietary Name:	**ABX PENTRA Deproteinizer CP**
Common or Usual Name:	Deproteinizer
Device Class	Class I : Exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Trade/Proprietary Name:	**ABX PENTRA Etching CP**
Common or Usual Name:	Etching
Device Class	Class I : Exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Substantial Equivalence:

The **ABX PENTRA 400** is a new device developed by HoribaABX. It has been demonstrated that the ABX PENTRA 400 can be considered substantially equivalent to the predicate device Roche Cobas Mira Plus (K920402).

The optional ISE module has been similarly demonstrated as being substantially equivalent to K963627; the Roche Ion Selective Electrode. Whilst the ABX PENTRA Glucose HK CP, and ABX PENTRA Glucose PAP CP have been demonstrated substantially equivalent to K801297; the Cobas Reagent for Glucose Rapid (K801297). ABX PENTRA Multical, ABX PENTRA N Control and ABX PENTRA P Control have been respectively demonstrated as being substantially equivalent to K033501, Roche Calibrator for Automated Systems and K0411227, Roche Precinorm U and Roche Precipath U.

Description:
The **ABX PENTRA 400** is a benchtop clinical chemistry analyzer using two measuring principals absorbance and ion selective electrodes.
The instrument may be summarized as follows :

- Multi-parametric (up to 52 simultaneous tests + 3 ISE tests)
- Patient per patient
- On routine or Stat
- 150 to 300 tests / hour (in single or bi-reaction mode) (analytical cycle of 12seconds)
- random access working on primary tubes or sample cups
- ABX PENTRA reagent cassettes are compact and ready-to-use.
- on board bar-code readers are used to identify newly loaded reagent cassettes and samples for patient identification

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).

Intended Use :

The **ABX PENTRA 400** is a discrete photometric benchtop chemistry analyzer for clinical use.
The device is intended to duplicate manual analytical procedures by performing various steps such as pipetting, mixing, heating and measuring color intensity.

The device is intended for use in conjunction with certain materials to measure, control and calibrate a variety of analytes.

The option of an ISE (Ion Selective Electrode) module is intended for the quantitative determination of Sodium, Chloride, Potassium by potentiometry using ion selective electrode.

Discussion of Performance Data:

ABX PENTRA Glucose HK CP:	
Sample type	Serum & plasma
Detection limit	1.98 mg/dl
Accuracy and Precision	CV Total < 2.03%
Measuring range	1.98 mg/dl – 900 mg/dl Automatic post-dilution : 2700 mg/dl
Correlation (n=103)	Y = 0.93 x + 2.70 with a correlation coefficient r^2 = 0.9958.
Calibration stability	14 days
Reagent stability	on-board stability (refrigerated area): 55 days
Calibrator	ABX Pentra Multical
Controls	ABX Pentra N Control ABX Pentra P Control

ABX PENTRA Glucose PAP CP:	
Sample type	Serum & plasma
Detection limit	1.80 mg/dl
Accuracy and Precision	CV Total < 1.44 %
Measuring range	1.80 mg/dl – 432 mg/dl With automatic post-dilution : 1296 mg/dl
Correlation (n=103)	Y = 0.98 x + 0.72 with a correlation coefficient r^2 = 0.9974.
Calibration stability	11 days
Reagent stability	on-board stability (refrigerated area): 83 days
Calibrator	ABX Pentra Multical
Controls	ABX Pentra N Control ABX Pentra P Control

ABX PENTRA Chloride– E :	
Sample type	Serum, plasma & urine
Accuracy and Precision	CV Total < 1.21 %
Linearity & Measuring range	Plasma / Serum : 85 – 200 mmol/l Urine : 70 – 300 mmol/l
Correlation Serum / Plasma (n=152) Urine (n=103)	 Y = 1.09 x - 10.60 with a correlation coefficient r^2 = 0.9651. Y = 0.99 x + 2.64 with a correlation coefficient r^2 = 0.9730.
Calibrators	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference
Controls	ABX Pentra N Control ABX Pentra P Control

ABX PENTRA Potassium– E :	
Sample type	Serum, plasma & urine
Accuracy and Precision	CV Total < 1.56 %
Linearity & Measuring range	Plasma / Serum : 1.4 – 10 mmol/l Urine : 2 – 150 mmol/l
Correlation Serum (n=100) Plasma (n=100) Urine (n=103)	 Y = 1.00 x + 0.00 with a correlation coefficient r^2 = 0.9988. Y = 1.00 x + 0.00 with a correlation coefficient r^2 = 0.9977. Y = 1.03 x - 0.72 with a correlation coefficient r^2 = 0.9753.
Calibrators	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference
Controls	ABX Pentra N Control ABX Pentra P Control

ABX PENTRA Sodium – E :	
Sample type	Serum, plasma & urine
Accuracy and Precision	CV Total < 0.92 %
Linearity & Measuring range	Plasma / Serum : 110 – 200 mmol/l Urine : 80 – 300 mmol/l
Correlation Serum (n=100) Plasma (n=100) Urine (n=103)	 Y = 0.98 x + 2.64 with a correlation coefficient r^2 = 0.9991. Y = 0.97 x + 4.77 with a correlation coefficient r^2 = 0.9960. Y = 1.00 x + 1.00 with a correlation coefficient r^2 = 0.9851.
Calibrators	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference
Controls	ABX Pentra N Control ABX Pentra P Control

Conclusions for non clinical and clinical tests :
The non clinical studies tests conclude that the safety and effectiveness of the devices are not compromised.

The **ABX PENTRA 400 (Option ISE)** meets the :

- **IEC 61010-1 :** safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- **EN 61326 :** standard for Electrical equipment for measurement, control and laboratory use - EMC requirements
- **UL 3101 – 1 / CSA – C22.2 No. 1010-1 :** Safety Requirements for Electrical Equipement for measurement, control, and laboratory use, Part 1 : General Requirements

Clinical testing met all acceptance criteria, and data demonstrates that the devices are substantially equivalent to their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 16 2005

Mr. Tim Lawton
Regulatory Affairs Manager
Horiba ABX
Parc Euromèdecine
Rue du Caducèe – BP 7290
34184 Montpellier cedex 4
France

Re: k052007
Trade/Device Name: ABX PENTRA 400 Clinical Chemistry Analyzers
ABX PENTRA 400 Calibrators and Controls
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR, JGS, CEM, CGZ, JIX, JJY, JJE
Dated: November 16, 2005
Received: November 21, 2005

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): K052007

Device Name: ABX PENTRA 400 Clinical Chemistry Analyzer
Option : I.S.E. module

Indications For Use:

The ABX PENTRA 400 is a discrete photometric benchtop chemistry analyzer for clinical use.
The device is intended to duplicate manual analytical procedures by performing various steps such as pipetting, mixing, heating and measuring color intensity.

The device is intended for use in conjunction with certain materials to measure a variety of analytes.

ABX PENTRA Glucose HK CP, Glucose PAP CP reagents with associated calibrators and controls are for quantitative in vitro diagnostic determination of glucose in serum and plasma using glucose hexokinase and glucose oxidase methods 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.

The option of an I.S.E. (Ion Selective Electrode) module is intended for the quantitative determination of Sodium, Chloride, and Potassium by potentiometry using ion selective electrode with associated reference solution, calibrators and controls. Measurement of Sodium, Chloride, and Potassium are used in diagnosis and treatment diseases involving electrolyte imbalance.

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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K052007

Indications for Use

510(k) Number (if known): K052007

Device Name: ABX PENTRA Multical

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

Division of In Vitro Diagnostic Device
Evaluation and Safety

K052007

Indications for Use

510(k) Number (if known): K052007

Device Name: ABX PENTRA N Control

Indications For Use:

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

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)

Division of In Vitro Diagnostic Device
Evaluation and Safety

K052007

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Indications for Use

510(k) Number (if known): K052007

Device Name: ABX PENTRA P Control

Indications For Use:

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

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)

Division of In Vitro Diagnostic Device
Evaluation and Safety

K052007