NOV 28 2011

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 : K103788

Company: Horiba ABX SAS
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Contact Person: Caroline Ferrer (caroline.ferrer@horiba.com)

Date Prepared: 07th September 2011

Device Name:

Trade/Proprietary Name:	**PENTRA C200**
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**
Common or Usual Name:	Ion Selective Electrode
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:	**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

The **PENTRA C200** is a new device developed in a joint-venture by HORIBA Medical, and commercialized under HORIBA ABX SAS manufacturer responsibility. HORIBA ABX SAS is the registered company name. Our company is part of the Medical segment of HORIBA group. Trade name of our activity is HORIBA Medical.

Predicate Devices:
The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices:

Candidate device	Predicate device	
	510(k) number	Device name
PENTRA C200	K052007	ABX PENTRA 400
PENTRA C200 I.S.E. Module	K052007	ABX PENTRA 400 I.S.E. Module
ABX PENTRA Glucose HK CP	K052007	ABX Pentra Glucose HK CP

Similarities and Differences between the predicate devices and candidate devices:

Table1: Comparison between PENTRA C200 and ABX PENTRA 400 (K052007)

	Predicate device	Candidate device
Device Name	**ABX PENTRA 400**	**PENTRA C200**
Instrument Type Separate workstation Touch Screen Interface	Benchtop No Yes	Same No Yes
Intended Use	Discrete photometric benchtop chemistry analyzer for clinical use	Same
Maximum throughput	420 Tests/Hour	360 Tests/Hour
Methodologies	Spectrophotometry Mono and Bi-chromatic measurement of light absorbance Potentiometry (for I.S.E. Module)	Same Same Same
STAT Capability	Yes	Yes
Sample ID Input	Barcoded ID Manual	Same
Reagent Barcode Reader	Integrated	Same
Reagent Positions	Up to 52 positions + 3 I.S.E.	Up to 15 positions + 3 I.S.E.
Sample Positions	Up to 60 samples	Up to 15 positions

Table 2: Comparison between PENTRA C200 I.S.E. Module and ABX PENTRA 400 I.S.E. Module (K052007)

	Predicate device	Candidate device
Device Name	**I.S.E. Module**	**I.S.E. Module**
Instrument	ABX PENTRA 400	PENTRA C200
Optional	Yes	Yes
Parameters	Na, K, Cl	Same
Potentiometry	Direct and Indirect	Same
Material **Sodium Electrode** **Potassium Electrode** **Chloride Electrode**	 Glass membrane selective to Na+ ions Plastic membrane selective to K+ ions Plastic membrane selective to Cl- ions	 Same Same Same
Specimen Types	Serum Plasma Urine	Same

Table 3: Comparison between Glucose HK assay on PENTRA C200 and on ABX PENTRA 400 (K052007)

	Predicate device	Candidate device
Device Name	**ABX PENTRA Glucose HK CP**	**ABX PENTRA Glucose HK CP**
Instrument	ABX PENTRA 400	PENTRA C200
Parameter	Glucose	Glucose
Method	Enzymatic method using hexokinase couple with glucose-6-phosphate dehydrogenase	Same
Material	Bi-reagent cassette, ready-to-use Reagent 1: NAD, ATP, Buffern Sodium azide Reagent 2: Hexokinase, G-6-PDH, Magnesium sulphate, Sodium azide	Same
Specimen Types	Serum Plasma Urine	Serum Plasma

Substantial Equivalence:

It has been demonstrated that the PENTRA C200 can be considered substantially equivalent to the predicate device ABX PENTRA 400 (K052007).

The I.S.E. module has been similarly demonstrated as being substantially equivalent to the predicate device K052007.

The ABX PENTRA Glucose HK CP used on the PENTRA C200 has been demonstrated substantially equivalent to the same reagent used on the ABX PENTRA 400 as described in K052007.

Description:

The **PENTRA C200** is a benchtop clinical chemistry analyzer using two measuring principles: absorbance and ion selective electrodes.
The instrument may be summarized as follows :

- Multi-parametric (up to 15 simultaneous tests + 3 ISE tests)
- On routine or Stat
- 90 (without ISE) to 360 (with ISE) tests / hour (in single or bi-reaction mode) (analytical cycle of 40 seconds)
- random access working on primary tubes or sample cups
- ABX PENTRA reagent cassettes are compact and ready-to-use.
- on board bar-code reader is used to identify newly loaded reagent cassettes and samples for patient identification

Intended Use / Indications for use :

The **PENTRA C200** is a discrete photometric benchtop chemistry analyzer for use in clinical laboratories. It is not intended for use in Point of Care settings.
It duplicates manual analytical procedures by performing various steps such as pipetting, mixing, heating and measuring color intensity. The **PENTRA C200** is intended for quantitative measurements of a variety of analytes: Glucose, Sodium, Potassium and Chloride.

ABX Pentra Glucose HK CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of glucose in serum and plasma 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.

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

Discussion of Performance Data:

ABX PENTRA Glucose HK CP:	
Sample type	Serum & plasma
Limit of Quantitation	5 mg/dL
Accuracy and Precision	CV Total ≤ 1.99%
Measuring range	5 mg/dL – 900 mg/dL Automatic post-dilution : 2700 mg/dL
Correlation (n=103)	Y = 0.98 x + 4.46 (mg/dL) with r^2 = 0.998.
Calibration stability	20 days
Reagent stability	On-board stability (refrigerated area): 39 days
Calibrator	ABX Pentra Multical
Controls	ABX Pentra N Control ABX Pentra P Control

ABX PENTRA Sodium – E :		
Sample type	Serum & plasma	Urine
Accuracy and Precision	CV Total ≤ 1.1 %	CV Total ≤ 4.91 %
Linearity & Measuring range	90 – 190 mmol/L	60 – 280 mmol/L
Correlation	Serum (n=129) Y = 0.96 x + 6.42 with r^2 = 0.982. Plasma (n=132) Y = 1.05 x - 5.32 with r^2 = 0.998.	Urine (n=101) Y = 1.01 x - 2.20 with r^2 = 0.989.
Calibrators	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference
Controls	ABX Pentra N Control ABX Pentra P Control	ABX Pentra N Control ABX Pentra P Control

ABX PENTRA Potassium – E :		
Sample type	Serum & plasma	Urine
Accuracy and Precision	CV Total ≤ 1.07 %	CV Total ≤ 2.87 %
Linearity & Measuring range	2 – 9.5 mmol/L	25 – 250 mmol/L
Correlation	Serum (n=122) Y = 1.01 x - 0.06 with r^2 = 0.998. Plasma (n=125) Y = 1.01 x - 0.09 with r^2 = 0.998.	Urine (n=159) Y = 1.02 x - 0.27 with r^2 = 0.997.
Calibrators	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference
Controls	ABX Pentra N Control ABX Pentra P Control	ABX Pentra N Control ABX Pentra P Control

ABX PENTRA Chloride – E :		
Sample type	Serum & plasma	Urine
Accuracy and Precision	CV Total ≤ 1.55 %	CV Total ≤ 4.59 %
Linearity & Measuring range	70 – 170 mmol/L	70 – 280 mmol/L
Correlation	Serum (n=170) Y = 0.96 x + 3.74 with r^2 = 0.996. Plasma (n=131) Y = 1.04 x - 4.17 with r^2 = 0.997.	Urine (n=112) Y = 1.04 x - 5.63 with r^2 = 0.987.
Calibrators	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference	ABX Pentra Standard 1 ABX Pentra Standard 2 ABX Pentra Reference
Controls	ABX Pentra N Control ABX Pentra P Control	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 **PENTRA C200 (with ISE module)** meets :

- **IEC 61010-1 / IEC 61010-2-081 / IEC 61010-2-101 :**

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 1: General requirements
Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

- **EN 61326-2-6 :**

Standard for Electrical equipment for measurement, control and laboratory use - EMC requirements
Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical device

- **UL631010 – 1 / CSA – C22.2 No. 61010-1 :**

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 & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Horiba ABX SAS
c/o Ms. Caroline Ferrer
Regulatory Affairs Specialist
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Rue du Caducee – BP 7290
34184 Montpellier cedex 4
France

NOV - 8 2011

Re: k103788
Trade Name: PENTRA C200, I.S.E. Module, and ABX PENTRA Glucose HK CP
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: CFR, JGS, CEM, CGZ, JJE
Dated: November 4 , 2011
Received: November 7 , 2011

Dear Ms. Ferrer:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, 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 Form

510(k) Number (if known): K103788

Device Name: PENTRA C200, I.S.E. Module, and ABX Pentra Glucose HK CP

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Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and odiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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

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

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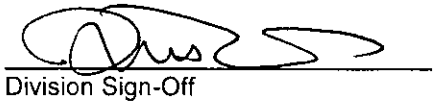
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



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

510(k) K103788